

**APPENDIX 2.1 Cumulative Number of Case Reports (Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class**

BNT162B2 - ALL

Reporting Period: Through 15-APR-2022

Total Number of Cases: 1,348,079 (100 %) (ALL) / (1,348,079) (OVERALL)

Total Number of Adverse Events (PT): 4,563,770 (ALL)

**NON-CT**

Total Number of Cases: 1,348,079

Total Number of Adverse Events (PT): 4,563,770

		Number of cases	Percentage (%)
<b>Sex</b>			
	FEMALE	923,194	68.5 %
	MALE	358,919	26.6 %
	NO DATA	64,781	4.8 %
	UNK	1,185	0.1 %
<b>Age Range</b>			
Min = 0.00 Years	0 to 27 days	280	0.0 %
Max = 121.00 Years	28 days to 23 months	2,022	0.1 %
Median = 43.00	2 to 11 years	8,374	0.6 %
Mean = 45.01	12 to 17 years	37,491	2.8 %
SD = 17.98	18 - 30 years	234,264	17.4 %
N = 1,198,699.00	31 - 50 years	491,221	36.4 %
	51 - 64 years	242,823	18.0 %
	65 - 74 years	102,167	7.6 %
	Greater than or equal to 75 years	87,034	6.5 %
	N/A - age range only applies to post-birth patients	470	0.0 %
	Less than or equal to 17 years	1	0.0 %
	Unknown	141,932	10.5 %
<b>Country Where Event Occured</b>			
	UNITED KINGDOM	181,882	13.5 %
	GERMANY	177,335	13.2 %
	JAPAN	127,370	9.4 %
	UNITED STATES	126,159	9.4 %
	NETHERLANDS	123,732	9.2 %
	FRANCE	103,915	7.7 %
	ITALY	87,451	6.5 %
	AUSTRIA	65,194	4.8 %
	AUSTRALIA	40,866	3.0 %
	SPAIN	38,307	2.8 %
	SWEDEN	22,461	1.7 %
	MEXICO	20,134	1.5 %
	NORWAY	18,135	1.3 %
	DENMARK	16,402	1.2 %
	BELGIUM	15,218	1.1 %
	PHILIPPINES	14,955	1.1 %
	CANADA	13,878	1.0 %
	PORTUGAL	13,771	1.0 %
	MALAYSIA	13,650	1.0 %
	CZECH REPUBLIC	12,845	1.0 %
	IRELAND	11,368	0.8 %
	IRAQ	8,221	0.6 %
	POLAND	7,542	0.6 %
	FINLAND	7,388	0.5 %
	GREECE	7,252	0.5 %
	BRAZIL	5,493	0.4 %
	ROMANIA	5,450	0.4 %
	TAIWAN, PROVINCE OF CHINA	5,311	0.4 %
	LITHUANIA	4,246	0.3 %

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	Number of cases	Percentage (%)
CROATIA	4,186	0.3 %
SWITZERLAND	3,993	0.3 %
HUNGARY	3,760	0.3 %
ESTONIA	3,438	0.3 %
NEW ZEALAND	3,175	0.2 %
ISRAEL	3,023	0.2 %
SLOVENIA	2,928	0.2 %
ICELAND	2,826	0.2 %
HONG KONG	2,728	0.2 %
SOUTH AFRICA	2,150	0.2 %
LUXEMBOURG	1,800	0.1 %
SLOVAKIA	1,782	0.1 %
LATVIA	1,653	0.1 %
EGYPT	1,388	0.1 %
TURKEY	1,239	0.1 %
BULGARIA	1,152	0.1 %
PANAMA	1,148	0.1 %
SERBIA	990	0.1 %
COSTA RICA	986	0.1 %
COLOMBIA	787	0.1 %
BAHRAIN	752	0.1 %
GEORGIA	682	0.1 %
CYPRUS	626	0.0 %
SINGAPORE	542	0.0 %
KOREA, REPUBLIC OF (SOUTH KOREA)	452	0.0 %
CHILE	382	0.0 %
PUERTO RICO	349	0.0 %
MALTA	282	0.0 %
ARGENTINA	279	0.0 %
SAUDI ARABIA	249	0.0 %
PERU	210	0.0 %
UNITED ARAB EMIRATES	202	0.0 %
THAILAND	171	0.0 %
LEBANON	159	0.0 %
MACEDONIA, THE FORMER YUGOSLAV REPUBLIC OF	152	0.0 %
ECUADOR	131	0.0 %
COOK ISLANDS	104	0.0 %
KUWAIT	88	0.0 %
JORDAN	85	0.0 %
INDONESIA	77	0.0 %
UKRAINE	75	0.0 %
VIET NAM	70	0.0 %
MACAO	69	0.0 %
QATAR	59	0.0 %
MONTENEGRO	58	0.0 %
BRUNEI DARUSSALAM	56	0.0 %
TUNISIA	53	0.0 %
MOROCCO	40	0.0 %
URUGUAY	39	0.0 %
BOSNIA AND HERZEGOVINA	25	0.0 %
INDIA	23	0.0 %
NEW CALEDONIA	22	0.0 %
MOLDOVA	20	0.0 %
PAKISTAN	20	0.0 %
TONGA	19	0.0 %
ALBANIA	18	0.0 %
BERMUDA	18	0.0 %
IRAN, ISLAMIC REPUBLIC OF	15	0.0 %
OMAN	15	0.0 %
DOMINICAN REPUBLIC	14	0.0 %
SAMOA	14	0.0 %

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	Number of cases	Percentage (%)
CAYMAN ISLANDS	12	0.0 %
NIUE	12	0.0 %
PARAGUAY	12	0.0 %
AFGHANISTAN	11	0.0 %
EL SALVADOR	11	0.0 %
TURKS AND CAICOS ISLANDS	11	0.0 %
UNITED STATES MINOR OUTLYING ISLANDS	11	0.0 %
AZERBAIJAN	10	0.0 %
FRENCH POLYNESIA	9	0.0 %
HONDURAS	9	0.0 %
BOLIVIA	8	0.0 %
GUAM	8	0.0 %
GUATEMALA	8	0.0 %
REUNION	8	0.0 %
TRINIDAD AND TOBAGO	8	0.0 %
KAZAKHSTAN	7	0.0 %
CHINA	6	0.0 %
KENYA	6	0.0 %
LIECHTENSTEIN	6	0.0 %
PALESTINIAN TERRITORY,OCCUPIED	6	0.0 %
BANGLADESH	5	0.0 %
GIBRALTAR	5	0.0 %
BARBADOS	4	0.0 %
CURACAO	4	0.0 %
GUERNSEY	4	0.0 %
ISLE OF MAN	4	0.0 %
NORTHERN MARIANA ISLANDS	4	0.0 %
RUSSIAN FEDERATION	4	0.0 %
SRI LANKA	4	0.0 %
VIRGIN ISLANDS, U.S.	4	0.0 %
ALGERIA	3	0.0 %
AMERICAN SAMOA	3	0.0 %
ANDORRA	3	0.0 %
ANGOLA	3	0.0 %
CAMEROON	3	0.0 %
CUBA	3	0.0 %
DOMINICA	3	0.0 %
JERSEY	3	0.0 %
UGANDA	3	0.0 %
BOTSWANA	2	0.0 %
COTE D'IVOIRE	2	0.0 %
ETHIOPIA	2	0.0 %
FALKLAND ISLANDS (MALVINAS)	2	0.0 %
FRENCH GUIANA	2	0.0 %
GUADELOUPE	2	0.0 %
HAITI	2	0.0 %
HOLY SEE (VATICAN CITY STATE)	2	0.0 %
JAMAICA	2	0.0 %
MAYOTTE	2	0.0 %
MONACO	2	0.0 %
MONGOLIA	2	0.0 %
VENEZUELA, BOLIVARIAN REPUBLIC OF	2	0.0 %
ZIMBABWE	2	0.0 %
ANGUILLA	1	0.0 %
ARUBA	1	0.0 %
BELARUS	1	0.0 %
BELIZE	1	0.0 %
BOUVENT ISLAND	1	0.0 %
BRITISH INDIAN OCEAN TERRITORY	1	0.0 %
CAMBODIA	1	0.0 %
CAPE VERDE	1	0.0 %

(continued)

		Number of cases	Percentage (%)
DJIBOUTI		1	0.0 %
FRENCH SOUTHERN TERRITORIES		1	0.0 %
GHANA		1	0.0 %
GRENADA		1	0.0 %
GUINEA		1	0.0 %
GUYANA		1	0.0 %
NEPAL		1	0.0 %
NICARAGUA		1	0.0 %
NIGERIA		1	0.0 %
RWANDA		1	0.0 %
SEYCHELLES		1	0.0 %
SYRIAN ARAB REPUBLIC		1	0.0 %
TOKELAU		1	0.0 %
TURKMENISTAN		1	0.0 %
UZBEKISTAN		1	0.0 %
ZAMBIA		1	0.0 %
<b>Source</b>			
Clinical Study		2,920	0.2 %
Literature - Non Study		2,143	0.2 %
Literature - Study		582	0.0 %
Solicited		2,331	0.2 %
Spontaneous		1,340,103	99.4 %
<b>Case Seriousness</b>			
SERIOUS		387,675	28.8 %
NONSERIOUS		960,404	71.2 %
<b>HP/Medically Confirmed</b>			
Yes		605,884	44.9 %
No		742,195	55.1 %
<b>Special Populations</b>			
<b>Pregnant/Breastfeeding Women</b>			
Yes		17,156	1.3 %
<b>Pediatric Non EIU</b>			
Yes		45,523	3.4 %
<b>Elderly</b>			
Yes		189,201	14.0 %
<b>Race/Ethnicity</b>			
ASIAN - HISPANIC OR LATINO		79	0.0 %
ASIAN - NO DATA		55,871	4.1 %
ASIAN - NOT HISPANIC OR LATINO		4,111	0.3 %
ASIAN - OTHER		13	0.0 %
BLACK - HISPANIC OR LATINO		178	0.0 %
BLACK - NO DATA		3,327	0.2 %
BLACK - NOT HISPANIC OR LATINO		2,231	0.2 %
BLACK - OTHER		41	0.0 %
CAUCASIAN - HISPANIC OR LATINO		2,529	0.2 %
CAUCASIAN - NO DATA		32,691	2.4 %
CAUCASIAN - NOT HISPANIC OR LATINO		30,940	2.3 %
CAUCASIAN - OTHER		213	0.0 %
NATIVE AMERICAN - HISPANIC OR LATINO		137	0.0 %
NATIVE AMERICAN - NO DATA		715	0.1 %
NATIVE AMERICAN - NOT HISPANIC OR LATINO		161	0.0 %
NATIVE AMERICAN - OTHER		8	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - HISPANIC OR LATINO		43	0.0 %
NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NO DATA		62	0.0 %

NATIVE HAWAIIAN / OTHER PACIFIC ISLANDER - NOT HISPANIC OR LATINO	94	0.0 %
NO DATA - HISPANIC OR LATINO	3,619	0.3 %
NO DATA - NO DATA	1,209,082	89.7 %
NO DATA - NOT HISPANIC OR LATINO	1,235	0.1 %
NO DATA - OTHER	699	0.1 %

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**NON-CT**

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Headache	Nervous system disorders	278527	20.66 %
Fatigue	General disorders and administration site conditions	219325	16.27 %
Pyrexia	General disorders and administration site conditions	213582	15.84 %
Vaccination site pain	General disorders and administration site conditions	180293	13.37 %
Myalgia	Musculoskeletal and connective tissue disorders	166298	12.34 %
Malaise	General disorders and administration site conditions	134951	10.01 %
Chills	General disorders and administration site conditions	120218	8.92 %
Nausea	Gastrointestinal disorders	117113	8.69 %
Arthralgia	Musculoskeletal and connective tissue disorders	114443	8.49 %
Pain in extremity	Musculoskeletal and connective tissue disorders	87021	6.46 %
Dizziness	Nervous system disorders	84502	6.27 %
Pain	General disorders and administration site conditions	75094	5.57 %
Lymphadenopathy	Blood and lymphatic system disorders	73287	5.44 %
COVID-19	Infections and infestations	61628	4.57 %
Asthenia	General disorders and administration site conditions	55694	4.13 %
Dyspnoea	Respiratory, thoracic and mediastinal disorders	51406	3.81 %
Off label use	Injury, poisoning and procedural complications	50005	3.71 %
Inappropriate schedule of product administration	Injury, poisoning and procedural complications	48662	3.61 %
Immunisation	Surgical and medical procedures	45975	3.41 %
Diarrhoea	Gastrointestinal disorders	41832	3.10 %
Paraesthesia	Nervous system disorders	40772	3.02 %
Rash	Skin and subcutaneous tissue disorders	38500	2.86 %
Vaccination site swelling	General disorders and administration site conditions	38085	2.83 %
Chest pain	General disorders and administration site conditions	37170	2.76 %
Vomiting	Gastrointestinal disorders	36026	2.67 %
Interchange of vaccine products	Surgical and medical procedures	34874	2.59 %
Pruritus	Skin and subcutaneous tissue disorders	34482	2.56 %
Drug ineffective	General disorders and administration site conditions	32823	2.43 %
Vaccination failure	General disorders and administration site conditions	31455	2.33 %
Heavy menstrual bleeding	Reproductive system and breast disorders	27685	2.05 %
Palpitations	Cardiac disorders	27157	2.01 %
Influenza like illness	General disorders and administration site conditions	26734	1.98 %
Hypoesthesia	Nervous system disorders	26646	1.98 %
Vaccination site erythema	General disorders and administration site conditions	26032	1.93 %
Cough	Respiratory, thoracic and mediastinal disorders	24597	1.82 %
Tachycardia	Cardiac disorders	22873	1.70 %
Menstrual disorder	Reproductive system and breast disorders	22145	1.64 %
Limb discomfort	Musculoskeletal and connective tissue disorders	21354	1.58 %
Erythema	Skin and subcutaneous tissue disorders	20881	1.55 %
Urticaria	Skin and subcutaneous tissue disorders	19749	1.46 %
Poor quality product administered	Injury, poisoning and procedural complications	19483	1.45 %
Chest discomfort	General disorders and administration site conditions	18472	1.37 %
Abdominal pain	Gastrointestinal disorders	18225	1.35 %
Back pain	Musculoskeletal and connective tissue disorders	18075	1.34 %
Oropharyngeal pain	Respiratory, thoracic and mediastinal disorders	17660	1.31 %
Herpes zoster	Infections and infestations	17259	1.28 %
Feeling hot	General disorders and administration site conditions	16682	1.24 %
Swelling	General disorders and administration site conditions	16073	1.19 %
Feeling abnormal	General disorders and administration site conditions	15947	1.18 %
Hyperhidrosis	Skin and subcutaneous tissue disorders	15825	1.17 %
Insomnia	Psychiatric disorders	15505	1.15 %
Vaccination site inflammation	General disorders and administration site conditions	15269	1.13 %
Menstruation irregular	Reproductive system and breast disorders	15083	1.12 %
Vaccination site warmth	General disorders and administration site conditions	15057	1.12 %
Peripheral swelling	General disorders and administration site conditions	14968	1.11 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Tinnitus	Ear and labyrinth disorders	14233	1.06 %
Vaccination site reaction	General disorders and administration site conditions	14107	1.05 %
Influenza	Infections and infestations	13994	1.04 %
Menstruation delayed	Reproductive system and breast disorders	13989	1.04 %
Dysmenorrhoea	Reproductive system and breast disorders	13904	1.03 %
Hypertension	Vascular disorders	13792	1.02 %
Axillary pain	General disorders and administration site conditions	13755	1.02 %
Product temperature excursion issue	Product issues	13516	1.00 %
Blood pressure increased	Investigations	13188	0.98 %
Somnolence	Nervous system disorders	13104	0.97 %
Syncope	Nervous system disorders	13056	0.97 %
Vertigo	Ear and labyrinth disorders	12888	0.96 %
Body temperature increased	Investigations	12618	0.94 %
Decreased appetite	Metabolism and nutrition disorders	12535	0.93 %
Intermenstrual bleeding	Reproductive system and breast disorders	12424	0.92 %
Neck pain	Musculoskeletal and connective tissue disorders	12182	0.90 %
Migraine	Nervous system disorders	11832	0.88 %
Amenorrhoea	Reproductive system and breast disorders	11363	0.84 %
Myocarditis	Cardiac disorders	11299	0.84 %
Feeling cold	General disorders and administration site conditions	10960	0.81 %
Abdominal pain upper	Gastrointestinal disorders	10880	0.81 %
Tremor	Nervous system disorders	10748	0.80 %
Heart rate increased	Investigations	10604	0.79 %
Muscular weakness	Musculoskeletal and connective tissue disorders	9785	0.73 %
Muscle spasms	Musculoskeletal and connective tissue disorders	9569	0.71 %
Polymenorrhoea	Reproductive system and breast disorders	9546	0.71 %
Sensitive skin	Skin and subcutaneous tissue disorders	9533	0.71 %
Vaccination site pruritus	General disorders and administration site conditions	9422	0.70 %
Pericarditis	Cardiac disorders	9186	0.68 %
Hypersensitivity	Immune system disorders	9035	0.67 %
Lethargy	Nervous system disorders	8954	0.66 %
Rhinorrhoea	Respiratory, thoracic and mediastinal disorders	8954	0.66 %
Lymph node pain	Blood and lymphatic system disorders	8395	0.62 %
Product use issue	Injury, poisoning and procedural complications	8170	0.61 %
Nasopharyngitis	Infections and infestations	8166	0.61 %
Musculoskeletal stiffness	Musculoskeletal and connective tissue disorders	8070	0.60 %
Vision blurred	Eye disorders	8042	0.60 %
Condition aggravated	General disorders and administration site conditions	8012	0.59 %
Arrhythmia	Cardiac disorders	7929	0.59 %
Presyncope	Nervous system disorders	7878	0.58 %
Injection site pain	General disorders and administration site conditions	7392	0.55 %
Loss of consciousness	Nervous system disorders	7261	0.54 %
Anaphylactic reaction	Immune system disorders	7214	0.54 %
Hot flush	Vascular disorders	7009	0.52 %
Gait disturbance	General disorders and administration site conditions	6973	0.52 %
Rash pruritic	Skin and subcutaneous tissue disorders	6870	0.51 %
Pulmonary embolism	Respiratory, thoracic and mediastinal disorders	6849	0.51 %
Illness	General disorders and administration site conditions	6671	0.49 %
Visual impairment	Eye disorders	6617	0.49 %
Anxiety	Psychiatric disorders	6571	0.49 %
Dysgeusia	Nervous system disorders	6501	0.48 %
Swelling face	General disorders and administration site conditions	6219	0.46 %
Burning sensation	Nervous system disorders	6083	0.45 %
Maternal exposure during pregnancy	Injury, poisoning and procedural complications	5823	0.43 %
Eye pain	Eye disorders	5754	0.43 %
Paraesthesia oral	Gastrointestinal disorders	5745	0.43 %
Exposure via breast milk	Injury, poisoning and procedural complications	5567	0.41 %
Discomfort	General disorders and administration site conditions	5545	0.41 %
Inflammation	General disorders and administration site conditions	5534	0.41 %
Disturbance in attention	Nervous system disorders	5511	0.41 %
Hypotension	Vascular disorders	5440	0.40 %
Confusional state	Psychiatric disorders	5191	0.39 %
Immunisation reaction	Immune system disorders	5151	0.38 %
Suspected COVID-19	Infections and infestations	5149	0.38 %
Acute stress disorder	Psychiatric disorders	5121	0.38 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Abdominal discomfort	Gastrointestinal disorders	5096	0.38 %
Epistaxis	Respiratory, thoracic and mediastinal disorders	4987	0.37 %
Contusion	Injury, poisoning and procedural complications	4971	0.37 %
Ear pain	Ear and labyrinth disorders	4868	0.36 %
Facial paralysis	Nervous system disorders	4856	0.36 %
Musculoskeletal pain	Musculoskeletal and connective tissue disorders	4856	0.36 %
Overdose	Injury, poisoning and procedural complications	4831	0.36 %
Breast pain	Reproductive system and breast disorders	4800	0.36 %
Vaginal haemorrhage	Reproductive system and breast disorders	4699	0.35 %
Neuralgia	Nervous system disorders	4639	0.34 %
Rash erythematous	Skin and subcutaneous tissue disorders	4610	0.34 %
Vaccination site lymphadenopathy	General disorders and administration site conditions	4540	0.34 %
Balance disorder	Nervous system disorders	4497	0.33 %
Deep vein thrombosis	Vascular disorders	4456	0.33 %
Thrombosis	Vascular disorders	4431	0.33 %
Incorrect route of product administration	Injury, poisoning and procedural complications	4391	0.33 %
Fall	Injury, poisoning and procedural complications	4321	0.32 %
Bone pain	Musculoskeletal and connective tissue disorders	4236	0.31 %
Sleep disorder	Psychiatric disorders	4217	0.31 %
Seizure	Nervous system disorders	4210	0.31 %
Head discomfort	Nervous system disorders	4181	0.31 %
Cerebrovascular accident	Nervous system disorders	4162	0.31 %
Vaccination site haematoma	General disorders and administration site conditions	4161	0.31 %
Ageusia	Nervous system disorders	3999	0.30 %
Lip swelling	Gastrointestinal disorders	3969	0.29 %
Cold sweat	Skin and subcutaneous tissue disorders	3928	0.29 %
Dysphagia	Gastrointestinal disorders	3889	0.29 %
Joint swelling	Musculoskeletal and connective tissue disorders	3864	0.29 %
Alopecia	Skin and subcutaneous tissue disorders	3831	0.28 %
Nasal congestion	Respiratory, thoracic and mediastinal disorders	3777	0.28 %
Mobility decreased	Musculoskeletal and connective tissue disorders	3737	0.28 %
Flushing	Vascular disorders	3720	0.28 %
Oedema peripheral	General disorders and administration site conditions	3710	0.28 %
Hypoesthesia oral	Gastrointestinal disorders	3637	0.27 %
Oedema	General disorders and administration site conditions	3582	0.27 %
Angina pectoris	Cardiac disorders	3491	0.26 %
Blood pressure decreased	Investigations	3452	0.26 %
Disease recurrence	General disorders and administration site conditions	3447	0.26 %
Oligomenorrhoea	Reproductive system and breast disorders	3437	0.25 %
Throat irritation	Respiratory, thoracic and mediastinal disorders	3389	0.25 %
Throat tightness	Respiratory, thoracic and mediastinal disorders	3369	0.25 %
Atrial fibrillation	Cardiac disorders	3285	0.24 %
Extensive swelling of vaccinated limb	General disorders and administration site conditions	3215	0.24 %
Bell's palsy	Nervous system disorders	3195	0.24 %
Vaccination site oedema	General disorders and administration site conditions	3185	0.24 %
Swollen tongue	Gastrointestinal disorders	3176	0.24 %
Night sweats	Skin and subcutaneous tissue disorders	3161	0.23 %
Anosmia	Nervous system disorders	3150	0.23 %
Pallor	Vascular disorders	3141	0.23 %
Asthma	Respiratory, thoracic and mediastinal disorders	3137	0.23 %
Loss of personal independence in daily activities	Social circumstances	3120	0.23 %
Muscle twitching	Musculoskeletal and connective tissue disorders	2961	0.22 %
Rash macular	Skin and subcutaneous tissue disorders	2931	0.22 %
Product preparation error	Injury, poisoning and procedural complications	2910	0.22 %
Death	General disorders and administration site conditions	2894	0.21 %
Oropharyngeal discomfort	Respiratory, thoracic and mediastinal disorders	2823	0.21 %
Expired product administered	Injury, poisoning and procedural complications	2806	0.21 %
Weight decreased	Investigations	2785	0.21 %
Product administration error	Injury, poisoning and procedural complications	2783	0.21 %
Vaccination site induration	General disorders and administration site conditions	2780	0.21 %
Movement disorder	Nervous system disorders	2736	0.20 %
Pneumonia	Infections and infestations	2728	0.20 %
Product administered to patient of inappropriate age	Injury, poisoning and procedural complications	2728	0.20 %
Dry mouth	Gastrointestinal disorders	2712	0.20 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Eye swelling	Eye disorders	2707	0.20 %
Oxygen saturation decreased	Investigations	2694	0.20 %
Underdose	Injury, poisoning and procedural complications	2657	0.20 %
Dysphonia	Respiratory, thoracic and mediastinal disorders	2648	0.20 %
Hypomenorrhoea	Reproductive system and breast disorders	2643	0.20 %
Memory impairment	Nervous system disorders	2633	0.20 %
Tenderness	General disorders and administration site conditions	2617	0.19 %
Abdominal distension	Gastrointestinal disorders	2610	0.19 %
Haematoma	Vascular disorders	2607	0.19 %
Oral herpes	Infections and infestations	2598	0.19 %
Photophobia	Eye disorders	2594	0.19 %
Myocardial infarction	Cardiac disorders	2581	0.19 %
Pharyngeal swelling	Respiratory, thoracic and mediastinal disorders	2577	0.19 %
Arthritis	Musculoskeletal and connective tissue disorders	2573	0.19 %
Peripheral coldness	Vascular disorders	2520	0.19 %
Eczema	Skin and subcutaneous tissue disorders	2484	0.18 %
Haemorrhage	Vascular disorders	2474	0.18 %
Vaccination site mass	General disorders and administration site conditions	2467	0.18 %
Dyspepsia	Gastrointestinal disorders	2465	0.18 %
Dyspnoea exertional	Respiratory, thoracic and mediastinal disorders	2458	0.18 %
Postmenopausal haemorrhage	Reproductive system and breast disorders	2456	0.18 %
Vaccination site movement impairment	General disorders and administration site conditions	2421	0.18 %
General physical health deterioration	General disorders and administration site conditions	2403	0.18 %
Taste disorder	Nervous system disorders	2403	0.18 %
Angioedema	Skin and subcutaneous tissue disorders	2393	0.18 %
Blister	Skin and subcutaneous tissue disorders	2353	0.17 %
Vaccination site rash	General disorders and administration site conditions	2308	0.17 %
C-reactive protein increased	Investigations	2251	0.17 %
Vaccination site discomfort	General disorders and administration site conditions	2207	0.16 %
Product preparation issue	Injury, poisoning and procedural complications	2188	0.16 %
Wheezing	Respiratory, thoracic and mediastinal disorders	2167	0.16 %
Sneezing	Respiratory, thoracic and mediastinal disorders	2160	0.16 %
Respiratory distress	Respiratory, thoracic and mediastinal disorders	2152	0.16 %
Lymphadenitis	Blood and lymphatic system disorders	2115	0.16 %
Abdominal pain lower	Gastrointestinal disorders	2109	0.16 %
Induration	General disorders and administration site conditions	2105	0.16 %
Pain in jaw	Musculoskeletal and connective tissue disorders	2097	0.16 %
Ocular hyperaemia	Eye disorders	2066	0.15 %
Speech disorder	Nervous system disorders	2061	0.15 %
Cardiovascular disorder	Cardiac disorders	2053	0.15 %
Nodule	General disorders and administration site conditions	2047	0.15 %
Ear discomfort	Ear and labyrinth disorders	2043	0.15 %
Irritability	Psychiatric disorders	2039	0.15 %
Restlessness	Psychiatric disorders	1990	0.15 %
Sensory disturbance	Nervous system disorders	1941	0.14 %
Feeling of body temperature change	General disorders and administration site conditions	1938	0.14 %
Joint range of motion decreased	Musculoskeletal and connective tissue disorders	1909	0.14 %
Thrombocytopenia	Blood and lymphatic system disorders	1907	0.14 %
Hypoacusis	Ear and labyrinth disorders	1905	0.14 %
Impaired work ability	Social circumstances	1905	0.14 %
Local reaction	General disorders and administration site conditions	1886	0.14 %
Thirst	General disorders and administration site conditions	1875	0.14 %
Therapeutic response unexpected	General disorders and administration site conditions	1872	0.14 %
Depression	Psychiatric disorders	1855	0.14 %
Fibrin D dimer increased	Investigations	1850	0.14 %
Asymptomatic COVID-19	Infections and infestations	1845	0.14 %
Depressed mood	Psychiatric disorders	1835	0.14 %
Parosmia	Nervous system disorders	1834	0.14 %
Pain of skin	Skin and subcutaneous tissue disorders	1810	0.13 %
Abortion spontaneous	Pregnancy, puerperium and perinatal conditions	1809	0.13 %
Heart rate irregular	Investigations	1808	0.13 %
Injected limb mobility decreased	General disorders and administration site conditions	1806	0.13 %
Petechiae	Skin and subcutaneous tissue disorders	1797	0.13 %
Disorientation	Psychiatric disorders	1777	0.13 %
Aphasia	Nervous system disorders	1773	0.13 %
Cardiac failure	Cardiac disorders	1770	0.13 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Product label confusion	Injury, poisoning and procedural complications	1769	0.13 %
Renal pain	Renal and urinary disorders	1745	0.13 %
Skin burning sensation	Skin and subcutaneous tissue disorders	1740	0.13 %
Musculoskeletal chest pain	Musculoskeletal and connective tissue disorders	1729	0.13 %
Hypersomnia	Nervous system disorders	1725	0.13 %
Cerebral infarction	Nervous system disorders	1723	0.13 %
Extrasystoles	Cardiac disorders	1686	0.13 %
Gait inability	General disorders and administration site conditions	1678	0.12 %
Facial paresis	Nervous system disorders	1638	0.12 %
Epilepsy	Nervous system disorders	1630	0.12 %
Skin discolouration	Skin and subcutaneous tissue disorders	1629	0.12 %
Urinary tract infection	Infections and infestations	1615	0.12 %
Dysarthria	Nervous system disorders	1614	0.12 %
Dysstasia	Nervous system disorders	1608	0.12 %
Eye pruritus	Eye disorders	1601	0.12 %
Neuropathy peripheral	Nervous system disorders	1601	0.12 %
Rash papular	Skin and subcutaneous tissue disorders	1599	0.12 %
Incorrect dose administered	Injury, poisoning and procedural complications	1593	0.12 %
Muscle tightness	Musculoskeletal and connective tissue disorders	1584	0.12 %
Pericardial effusion	Cardiac disorders	1581	0.12 %
Productive cough	Respiratory, thoracic and mediastinal disorders	1580	0.12 %
Diplopia	Eye disorders	1572	0.12 %
Dizziness postural	Nervous system disorders	1572	0.12 %
Hypokinesia	Nervous system disorders	1570	0.12 %
Vaccination site bruising	General disorders and administration site conditions	1569	0.12 %
Gastrointestinal disorder	Gastrointestinal disorders	1566	0.12 %
Dehydration	Metabolism and nutrition disorders	1561	0.12 %
Depressed level of consciousness	Nervous system disorders	1553	0.12 %
Transient ischaemic attack	Nervous system disorders	1549	0.11 %
COVID-19 pneumonia	Infections and infestations	1546	0.11 %
Face oedema	General disorders and administration site conditions	1544	0.11 %
Skin disorder	Skin and subcutaneous tissue disorders	1537	0.11 %
Amnesia	Nervous system disorders	1523	0.11 %
Facial pain	General disorders and administration site conditions	1504	0.11 %
Hypertensive crisis	Vascular disorders	1494	0.11 %
Application site pain	General disorders and administration site conditions	1490	0.11 %
Constipation	Gastrointestinal disorders	1482	0.11 %
Guillain-Barre syndrome	Nervous system disorders	1461	0.11 %
Lacrimation increased	Eye disorders	1455	0.11 %
Eye irritation	Eye disorders	1452	0.11 %
Cardiac arrest	Cardiac disorders	1443	0.11 %
Cardiac disorder	Cardiac disorders	1436	0.11 %
Panic attack	Psychiatric disorders	1436	0.11 %
Axillary mass	Musculoskeletal and connective tissue disorders	1428	0.11 %
Odynophagia	Gastrointestinal disorders	1419	0.11 %
Hemiparesis	Nervous system disorders	1411	0.10 %
Hyperaesthesia	Nervous system disorders	1380	0.10 %
Sensation of foreign body	General disorders and administration site conditions	1361	0.10 %
Rheumatoid arthritis	Musculoskeletal and connective tissue disorders	1356	0.10 %
Musculoskeletal discomfort	Musculoskeletal and connective tissue disorders	1351	0.10 %
Product storage error	Injury, poisoning and procedural complications	1350	0.10 %
Joint stiffness	Musculoskeletal and connective tissue disorders	1345	0.10 %
Breast swelling	Reproductive system and breast disorders	1339	0.10 %
Ischaemic stroke	Nervous system disorders	1339	0.10 %
Deafness	Ear and labyrinth disorders	1337	0.10 %
Toothache	Gastrointestinal disorders	1324	0.10 %
Circulatory collapse	Vascular disorders	1320	0.10 %
Nervousness	Psychiatric disorders	1309	0.10 %
Tension headache	Nervous system disorders	1282	0.10 %
Troponin increased	Investigations	1274	0.09 %
Poor quality sleep	Psychiatric disorders	1243	0.09 %
Heart rate decreased	Investigations	1240	0.09 %
Paralysis	Nervous system disorders	1240	0.09 %
Bradycardia	Cardiac disorders	1238	0.09 %
Psoriasis	Skin and subcutaneous tissue disorders	1235	0.09 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Sinusitis	Infections and infestations	1228	0.09 %
Swelling of eyelid	Eye disorders	1219	0.09 %
Blood glucose increased	Investigations	1218	0.09 %
Menstrual discomfort	Reproductive system and breast disorders	1199	0.09 %
Anaphylactic shock	Immune system disorders	1184	0.09 %
Exercise tolerance decreased	General disorders and administration site conditions	1181	0.09 %
Cardiac flutter	Cardiac disorders	1173	0.09 %
Ocular discomfort	Eye disorders	1170	0.09 %
Vaccination complication	Injury, poisoning and procedural complications	1149	0.09 %
Anaemia	Blood and lymphatic system disorders	1147	0.09 %
Hypotonia	Nervous system disorders	1145	0.08 %
Rhinitis	Infections and infestations	1142	0.08 %
Dermatitis allergic	Skin and subcutaneous tissue disorders	1135	0.08 %
Injection site erythema	General disorders and administration site conditions	1122	0.08 %
Gastrointestinal pain	Gastrointestinal disorders	1121	0.08 %
Spinal pain	Musculoskeletal and connective tissue disorders	1111	0.08 %
Cerebral haemorrhage	Nervous system disorders	1105	0.08 %
Acne	Skin and subcutaneous tissue disorders	1093	0.08 %
Hyperventilation	Respiratory, thoracic and mediastinal disorders	1083	0.08 %
Hyperpyrexia	General disorders and administration site conditions	1081	0.08 %
Infection	Infections and infestations	1081	0.08 %
Respiratory disorder	Respiratory, thoracic and mediastinal disorders	1075	0.08 %
SARS-CoV-2 test positive	Investigations	1062	0.08 %
Dysaesthesia	Nervous system disorders	1055	0.08 %
Hyperthermia	General disorders and administration site conditions	1054	0.08 %
Acute myocardial infarction	Cardiac disorders	1053	0.08 %
Bedridden	Social circumstances	1052	0.08 %
Dry skin	Skin and subcutaneous tissue disorders	1051	0.08 %
Pelvic pain	Reproductive system and breast disorders	1040	0.08 %
Maternal exposure timing unspecified	Injury, poisoning and procedural complications	1012	0.08 %
Flatulence	Gastrointestinal disorders	1010	0.07 %
Retching	Gastrointestinal disorders	1004	0.07 %
Nervous system disorder	Nervous system disorders	1001	0.07 %
Premenstrual syndrome	Reproductive system and breast disorders	998	0.07 %
Skin reaction	Skin and subcutaneous tissue disorders	991	0.07 %
Vaccination site paraesthesia	General disorders and administration site conditions	959	0.07 %
Platelet count decreased	Investigations	956	0.07 %
Wrong technique in product usage process	Injury, poisoning and procedural complications	956	0.07 %
Pulmonary pain	Respiratory, thoracic and mediastinal disorders	954	0.07 %
Cyanosis	Vascular disorders	950	0.07 %
Product administered at inappropriate site	Injury, poisoning and procedural complications	948	0.07 %
Cardiac discomfort	Cardiac disorders	943	0.07 %
Eyelid oedema	Eye disorders	943	0.07 %
Superficial vein thrombosis	Vascular disorders	939	0.07 %
Cognitive disorder	Nervous system disorders	936	0.07 %
Blood pressure fluctuation	Vascular disorders	932	0.07 %
Oral discomfort	Gastrointestinal disorders	923	0.07 %
Agitation	Psychiatric disorders	922	0.07 %
Stress	Psychiatric disorders	914	0.07 %
Muscle fatigue	Musculoskeletal and connective tissue disorders	902	0.07 %
Mouth ulceration	Gastrointestinal disorders	898	0.07 %
Pleural effusion	Respiratory, thoracic and mediastinal disorders	898	0.07 %
Blindness	Eye disorders	897	0.07 %
Conjunctivitis	Infections and infestations	890	0.07 %
Skin exfoliation	Skin and subcutaneous tissue disorders	890	0.07 %
Skin warm	Skin and subcutaneous tissue disorders	889	0.07 %
Pollakiuria	Renal and urinary disorders	888	0.07 %
Sensory loss	Nervous system disorders	886	0.07 %
Hallucination	Psychiatric disorders	883	0.07 %
Mass	General disorders and administration site conditions	880	0.07 %
Crying	General disorders and administration site conditions	876	0.06 %
Dry eye	Eye disorders	875	0.06 %
Concomitant disease aggravated	General disorders and administration site conditions	863	0.06 %
Rash maculo-papular	Skin and subcutaneous tissue disorders	862	0.06 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Aphthous ulcer	Gastrointestinal disorders	860	0.06 %
Dyskinesia	Nervous system disorders	854	0.06 %
Polymyalgia rheumatica	Musculoskeletal and connective tissue disorders	853	0.06 %
Tachypnoea	Respiratory, thoracic and mediastinal disorders	852	0.06 %
Gastroesophageal reflux disease	Gastrointestinal disorders	839	0.06 %
Immune thrombocytopenia	Blood and lymphatic system disorders	835	0.06 %
Aphonia	Respiratory, thoracic and mediastinal disorders	832	0.06 %
Feeding disorder	Metabolism and nutrition disorders	832	0.06 %
Altered state of consciousness	Nervous system disorders	829	0.06 %
Dermatitis	Skin and subcutaneous tissue disorders	822	0.06 %
Respiratory failure	Respiratory, thoracic and mediastinal disorders	819	0.06 %
Periorbital swelling	Eye disorders	817	0.06 %
Dry throat	Respiratory, thoracic and mediastinal disorders	816	0.06 %
Haematuria	Renal and urinary disorders	815	0.06 %
Abnormal faeces	Gastrointestinal disorders	803	0.06 %
Groin pain	Musculoskeletal and connective tissue disorders	802	0.06 %
Thrombophlebitis	Vascular disorders	801	0.06 %
Formication	Nervous system disorders	797	0.06 %
White blood cell count increased	Investigations	796	0.06 %
Eye disorder	Eye disorders	795	0.06 %
Breast tenderness	Reproductive system and breast disorders	792	0.06 %
Bronchospasm	Respiratory, thoracic and mediastinal disorders	787	0.06 %
Sinus tachycardia	Cardiac disorders	780	0.06 %
Acute kidney injury	Renal and urinary disorders	778	0.06 %
Lip oedema	Gastrointestinal disorders	773	0.06 %
Monoplegia	Nervous system disorders	773	0.06 %
Trigeminal neuralgia	Nervous system disorders	772	0.06 %
Sudden hearing loss	Ear and labyrinth disorders	769	0.06 %
Wrong product administered	Injury, poisoning and procedural complications	764	0.06 %
Ventricular extrasystoles	Cardiac disorders	760	0.06 %
Hyperacusis	Ear and labyrinth disorders	758	0.06 %
Dysuria	Renal and urinary disorders	755	0.06 %
Rash vesicular	Skin and subcutaneous tissue disorders	755	0.06 %
Photopsia	Eye disorders	752	0.06 %
Lymphoedema	Vascular disorders	751	0.06 %
Nightmare	Psychiatric disorders	751	0.06 %
Oral pain	Gastrointestinal disorders	750	0.06 %
Glossodynia	Gastrointestinal disorders	748	0.06 %
Weight increased	Investigations	742	0.06 %
Cardio-respiratory arrest	Cardiac disorders	738	0.05 %
Sciatica	Nervous system disorders	738	0.05 %
Migraine with aura	Nervous system disorders	729	0.05 %
Stomatitis	Gastrointestinal disorders	729	0.05 %
Cellulitis	Infections and infestations	727	0.05 %
Apathy	Psychiatric disorders	724	0.05 %
Injection site swelling	General disorders and administration site conditions	724	0.05 %
Purpura	Skin and subcutaneous tissue disorders	721	0.05 %
Haematochezia	Gastrointestinal disorders	719	0.05 %
Allergy to vaccine	Immune system disorders	716	0.05 %
Motor dysfunction	Nervous system disorders	708	0.05 %
Blepharospasm	Eye disorders	705	0.05 %
Hemiplegia	Nervous system disorders	695	0.05 %
Vaccination site hypoesthesia	General disorders and administration site conditions	694	0.05 %
Vaccination site urticaria	General disorders and administration site conditions	691	0.05 %
Urinary incontinence	Renal and urinary disorders	689	0.05 %
Venous thrombosis limb	Vascular disorders	689	0.05 %
Maternal exposure during breast feeding	Injury, poisoning and procedural complications	685	0.05 %
Vaccination error	Injury, poisoning and procedural complications	684	0.05 %
Lung disorder	Respiratory, thoracic and mediastinal disorders	683	0.05 %
Bronchitis	Infections and infestations	681	0.05 %
Sudden death	General disorders and administration site conditions	679	0.05 %
Mood swings	Psychiatric disorders	678	0.05 %
Electric shock sensation	Nervous system disorders	677	0.05 %
Middle insomnia	Psychiatric disorders	676	0.05 %
Fibromyalgia	Musculoskeletal and connective tissue disorders	674	0.05 %
Periarthritis	Musculoskeletal and connective tissue disorders	673	0.05 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Head injury	Injury, poisoning and procedural complications	670	0.05 %
Vasculitis	Vascular disorders	668	0.05 %
Mouth swelling	Gastrointestinal disorders	661	0.05 %
Administration site pain	General disorders and administration site conditions	660	0.05 %
Localised oedema	General disorders and administration site conditions	657	0.05 %
Deafness unilateral	Ear and labyrinth disorders	656	0.05 %
Muscle contractions involuntary	Nervous system disorders	656	0.05 %
Painful respiration	Respiratory, thoracic and mediastinal disorders	656	0.05 %
Blood pressure abnormal	Investigations	652	0.05 %
Ophthalmic herpes zoster	Infections and infestations	647	0.05 %
Asthenopia	Eye disorders	641	0.05 %
Cystitis	Infections and infestations	640	0.05 %
Heart rate abnormal	Investigations	639	0.05 %
Body temperature decreased	Investigations	636	0.05 %
Bursitis	Musculoskeletal and connective tissue disorders	635	0.05 %
Vaccination site haemorrhage	General disorders and administration site conditions	634	0.05 %
Menometrorrhagia	Reproductive system and breast disorders	632	0.05 %
Vaccination site joint pain	General disorders and administration site conditions	632	0.05 %
Appendicitis	Infections and infestations	628	0.05 %
Hormone level abnormal	Investigations	626	0.05 %
Renal failure	Renal and urinary disorders	625	0.05 %
Temperature regulation disorder	General disorders and administration site conditions	624	0.05 %
Generalised tonic-clonic seizure	Nervous system disorders	623	0.05 %
Respiration abnormal	Respiratory, thoracic and mediastinal disorders	618	0.05 %
Tongue discomfort	Gastrointestinal disorders	615	0.05 %
Vaccination site joint movement impairment	General disorders and administration site conditions	614	0.05 %
Skin lesion	Skin and subcutaneous tissue disorders	612	0.05 %
Adnexa uteri pain	Reproductive system and breast disorders	609	0.05 %
Electrocardiogram abnormal	Investigations	609	0.05 %
Papule	Skin and subcutaneous tissue disorders	605	0.04 %
Physical deconditioning	General disorders and administration site conditions	601	0.04 %
Hypoglycaemia	Metabolism and nutrition disorders	596	0.04 %
Phlebitis	Vascular disorders	596	0.04 %
Delirium	Psychiatric disorders	592	0.04 %
Immune system disorder	Immune system disorders	592	0.04 %
Peripheral vascular disorder	Vascular disorders	590	0.04 %
Body temperature abnormal	Investigations	587	0.04 %
Blood creatine phosphokinase increased	Investigations	586	0.04 %
Premenstrual pain	Reproductive system and breast disorders	585	0.04 %
Pityriasis rosea	Skin and subcutaneous tissue disorders	584	0.04 %
Sinus pain	Respiratory, thoracic and mediastinal disorders	582	0.04 %
Sepsis	Infections and infestations	577	0.04 %
Coordination abnormal	Nervous system disorders	576	0.04 %
Herpes virus infection	Infections and infestations	574	0.04 %
Mental impairment	Nervous system disorders	572	0.04 %
Skin irritation	Skin and subcutaneous tissue disorders	572	0.04 %
Vertigo positional	Ear and labyrinth disorders	572	0.04 %
Visual field defect	Eye disorders	572	0.04 %
Hypoxia	Respiratory, thoracic and mediastinal disorders	568	0.04 %
Flank pain	Musculoskeletal and connective tissue disorders	567	0.04 %
Eating disorder	Psychiatric disorders	565	0.04 %
COVID-19 immunisation	Surgical and medical procedures	562	0.04 %
Restless legs syndrome	Nervous system disorders	562	0.04 %
Haemoptysis	Respiratory, thoracic and mediastinal disorders	561	0.04 %
Photosensitivity reaction	Skin and subcutaneous tissue disorders	561	0.04 %
Tendonitis	Musculoskeletal and connective tissue disorders	552	0.04 %
Herpes simplex	Infections and infestations	551	0.04 %
Arthropathy	Musculoskeletal and connective tissue disorders	549	0.04 %
Colitis ulcerative	Gastrointestinal disorders	548	0.04 %
Abnormal dreams	Psychiatric disorders	547	0.04 %
Lower respiratory tract infection	Infections and infestations	547	0.04 %
Suppressed lactation	Reproductive system and breast disorders	545	0.04 %
Sinus headache	Nervous system disorders	538	0.04 %
Visual acuity reduced	Eye disorders	537	0.04 %
Ear infection	Infections and infestations	532	0.04 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Extra dose administered	Injury, poisoning and procedural complications	532	0.04 %
Feeling drunk	General disorders and administration site conditions	532	0.04 %
Blood pressure systolic increased	Investigations	529	0.04 %
Haemoglobin decreased	Investigations	526	0.04 %
Exposure during pregnancy	Injury, poisoning and procedural complications	524	0.04 %
Ecchymosis	Skin and subcutaneous tissue disorders	523	0.04 %
Eye haemorrhage	Eye disorders	523	0.04 %
Tonsillitis	Infections and infestations	523	0.04 %
Vestibular neuronitis	Infections and infestations	519	0.04 %
Multiple sclerosis	Nervous system disorders	517	0.04 %
Eye inflammation	Eye disorders	516	0.04 %
Mental fatigue	Psychiatric disorders	516	0.04 %
Myositis	Musculoskeletal and connective tissue disorders	515	0.04 %
Initial insomnia	Psychiatric disorders	514	0.04 %
Hyperglycaemia	Metabolism and nutrition disorders	512	0.04 %
Gastritis	Gastrointestinal disorders	508	0.04 %
Pulmonary oedema	Respiratory, thoracic and mediastinal disorders	508	0.04 %
Musculoskeletal disorder	Musculoskeletal and connective tissue disorders	504	0.04 %
Breast mass	Reproductive system and breast disorders	502	0.04 %
Gout	Metabolism and nutrition disorders	501	0.04 %
Pharyngeal paraesthesia	Respiratory, thoracic and mediastinal disorders	501	0.04 %
Monoparesis	Nervous system disorders	500	0.04 %
Limb injury	Injury, poisoning and procedural complications	499	0.04 %
Autoimmune disorder	Immune system disorders	496	0.04 %
Listless	Psychiatric disorders	496	0.04 %
Osteoarthritis	Musculoskeletal and connective tissue disorders	496	0.04 %
Vitreous floaters	Eye disorders	493	0.04 %
Gingival bleeding	Gastrointestinal disorders	492	0.04 %
Injection site pruritus	General disorders and administration site conditions	490	0.04 %
Laryngeal oedema	Respiratory, thoracic and mediastinal disorders	489	0.04 %
Quality of life decreased	Investigations	485	0.04 %
Breast enlargement	Reproductive system and breast disorders	483	0.04 %
Dysphoria	Psychiatric disorders	483	0.04 %
Hyperthyroidism	Endocrine disorders	483	0.04 %
Sluggishness	General disorders and administration site conditions	483	0.04 %
Impaired quality of life	Social circumstances	482	0.04 %
Seasonal allergy	Immune system disorders	481	0.04 %
Vaginal discharge	Reproductive system and breast disorders	480	0.04 %
Cerebral venous sinus thrombosis	Nervous system disorders	479	0.04 %
Cluster headache	Nervous system disorders	476	0.04 %
Circumstance or information capable of leading to medication error	Injury, poisoning and procedural complications	475	0.04 %
Tongue oedema	Gastrointestinal disorders	470	0.03 %
Chromaturia	Renal and urinary disorders	469	0.03 %
Fear	Psychiatric disorders	468	0.03 %
Blood urine present	Investigations	467	0.03 %
Injection site reaction	General disorders and administration site conditions	463	0.03 %
Alanine aminotransferase increased	Investigations	458	0.03 %
Coagulopathy	Blood and lymphatic system disorders	458	0.03 %
Pharyngitis	Infections and infestations	458	0.03 %
Venous thrombosis	Vascular disorders	455	0.03 %
Eyelid ptosis	Eye disorders	453	0.03 %
Mood altered	Psychiatric disorders	453	0.03 %
Varicose vein	Vascular disorders	451	0.03 %
Erectile dysfunction	Reproductive system and breast disorders	449	0.03 %
Gingival pain	Gastrointestinal disorders	449	0.03 %
Neurological symptom	Nervous system disorders	449	0.03 %
Shock	Vascular disorders	448	0.03 %
Costochondritis	Musculoskeletal and connective tissue disorders	446	0.03 %
Breast discomfort	Reproductive system and breast disorders	443	0.03 %
Polyneuropathy	Nervous system disorders	441	0.03 %
Respiratory rate increased	Investigations	439	0.03 %
Hypothermia	General disorders and administration site conditions	437	0.03 %
Multiple sclerosis relapse	Nervous system disorders	435	0.03 %
Nerve injury	Injury, poisoning and procedural complications	434	0.03 %
Alopecia areata	Skin and subcutaneous tissue disorders	433	0.03 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Erythema multiforme	Skin and subcutaneous tissue disorders	433	0.03 %
Optic neuritis	Nervous system disorders	431	0.03 %
Fluid retention	Metabolism and nutrition disorders	428	0.03 %
Rheumatic disorder	Musculoskeletal and connective tissue disorders	425	0.03 %
Mental disorder	Psychiatric disorders	423	0.03 %
Rectal haemorrhage	Gastrointestinal disorders	420	0.03 %
Drug hypersensitivity	Immune system disorders	415	0.03 %
Unresponsive to stimuli	Nervous system disorders	415	0.03 %
Diabetes mellitus	Metabolism and nutrition disorders	413	0.03 %
Drug interaction	General disorders and administration site conditions	413	0.03 %
Supraventricular tachycardia	Cardiac disorders	412	0.03 %
Performance status decreased	General disorders and administration site conditions	410	0.03 %
Skin swelling	Skin and subcutaneous tissue disorders	409	0.03 %
Eructation	Gastrointestinal disorders	408	0.03 %
Conjunctival haemorrhage	Eye disorders	407	0.03 %
Muscle strain	Injury, poisoning and procedural complications	407	0.03 %
SARS-CoV-2 antibody test negative	Investigations	403	0.03 %
Vaccination site discolouration	General disorders and administration site conditions	402	0.03 %
Gastroenteritis	Infections and infestations	398	0.03 %
Oral pruritus	Gastrointestinal disorders	398	0.03 %
Viral infection	Infections and infestations	397	0.03 %
Vascular pain	Vascular disorders	396	0.03 %
Genital herpes	Infections and infestations	395	0.03 %
Pleurisy	Respiratory, thoracic and mediastinal disorders	395	0.03 %
Hemiparaesthesia	Nervous system disorders	394	0.03 %
Grip strength decreased	Investigations	393	0.03 %
Paresis	Nervous system disorders	393	0.03 %
Tension	Psychiatric disorders	393	0.03 %
Mastitis	Infections and infestations	392	0.03 %
White blood cell count decreased	Investigations	391	0.03 %
Salivary hypersecretion	Gastrointestinal disorders	389	0.03 %
Hypothyroidism	Endocrine disorders	387	0.03 %
Nasal discomfort	Respiratory, thoracic and mediastinal disorders	387	0.03 %
Drug eruption	Skin and subcutaneous tissue disorders	386	0.03 %
Dysentery	Infections and infestations	386	0.03 %
Raynaud's phenomenon	Vascular disorders	386	0.03 %
Retinal vein occlusion	Eye disorders	386	0.03 %
Pharyngeal oedema	Respiratory, thoracic and mediastinal disorders	379	0.03 %
Acute coronary syndrome	Cardiac disorders	378	0.03 %
Electrocardiogram ST segment elevation	Investigations	378	0.03 %
Subarachnoid haemorrhage	Nervous system disorders	378	0.03 %
Muscle rigidity	Musculoskeletal and connective tissue disorders	377	0.03 %
Tonsillar hypertrophy	Respiratory, thoracic and mediastinal disorders	374	0.03 %
Weight bearing difficulty	Musculoskeletal and connective tissue disorders	374	0.03 %
Pustule	Infections and infestations	373	0.03 %
Basedow's disease	Endocrine disorders	372	0.03 %
Renal impairment	Renal and urinary disorders	372	0.03 %
Aspartate aminotransferase increased	Investigations	369	0.03 %
Ear swelling	Ear and labyrinth disorders	367	0.03 %
Colitis	Gastrointestinal disorders	366	0.03 %
Respiratory arrest	Respiratory, thoracic and mediastinal disorders	364	0.03 %
Testicular pain	Reproductive system and breast disorders	362	0.03 %
Emotional disorder	Psychiatric disorders	360	0.03 %
Neuritis	Nervous system disorders	358	0.03 %
Body temperature fluctuation	Investigations	356	0.03 %
Hepatic function abnormal	Hepatobiliary disorders	355	0.03 %
Cardiomegaly	Cardiac disorders	354	0.03 %
Cerebral thrombosis	Nervous system disorders	354	0.03 %
Hypopnoea	Respiratory, thoracic and mediastinal disorders	354	0.03 %
Ataxia	Nervous system disorders	353	0.03 %
Chronic obstructive pulmonary disease	Respiratory, thoracic and mediastinal disorders	351	0.03 %
Emotional distress	Psychiatric disorders	350	0.03 %
Tongue disorder	Gastrointestinal disorders	350	0.03 %
Micturition urgency	Renal and urinary disorders	349	0.03 %
Suicidal ideation	Psychiatric disorders	349	0.03 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Hepatic enzyme increased	Investigations	347	0.03 %
Myelitis	Infections and infestations	347	0.03 %
Ovulation pain	Reproductive system and breast disorders	347	0.03 %
Faeces discoloured	Gastrointestinal disorders	345	0.03 %
Tendon pain	Musculoskeletal and connective tissue disorders	345	0.03 %
Crohn's disease	Gastrointestinal disorders	342	0.03 %
Thinking abnormal	Psychiatric disorders	341	0.03 %
Pancreatitis acute	Gastrointestinal disorders	339	0.03 %
Red blood cell sedimentation rate increased	Investigations	339	0.03 %
Endometriosis	Reproductive system and breast disorders	337	0.02 %
Blood glucose decreased	Investigations	335	0.02 %
Atrial flutter	Cardiac disorders	334	0.02 %
Coma	Nervous system disorders	334	0.02 %
Pleuritic pain	Respiratory, thoracic and mediastinal disorders	333	0.02 %
Eye movement disorder	Eye disorders	330	0.02 %
Feeling jittery	General disorders and administration site conditions	330	0.02 %
Maternal exposure before pregnancy	Injury, poisoning and procedural complications	329	0.02 %
Pulmonary thrombosis	Respiratory, thoracic and mediastinal disorders	326	0.02 %
Urinary retention	Renal and urinary disorders	326	0.02 %
Erysipelas	Infections and infestations	325	0.02 %
Embolism	Vascular disorders	324	0.02 %
Vasodilatation	Vascular disorders	324	0.02 %
Encephalitis	Infections and infestations	323	0.02 %
Interstitial lung disease	Respiratory, thoracic and mediastinal disorders	321	0.02 %
Paranasal sinus discomfort	Respiratory, thoracic and mediastinal disorders	320	0.02 %
Hunger	General disorders and administration site conditions	319	0.02 %
Uveitis	Eye disorders	319	0.02 %
Oral mucosal blistering	Gastrointestinal disorders	317	0.02 %
Pulse abnormal	Investigations	314	0.02 %
Panic reaction	Psychiatric disorders	313	0.02 %
Polyarthritis	Musculoskeletal and connective tissue disorders	312	0.02 %
Accidental overdose	Injury, poisoning and procedural complications	311	0.02 %
Chronic fatigue syndrome	General disorders and administration site conditions	311	0.02 %
Impaired driving ability	Social circumstances	311	0.02 %
Sinus congestion	Respiratory, thoracic and mediastinal disorders	311	0.02 %
Jaundice	Hepatobiliary disorders	308	0.02 %
Menstrual cycle management	Surgical and medical procedures	308	0.02 %
Neck mass	Musculoskeletal and connective tissue disorders	308	0.02 %
Erythema nodosum	Skin and subcutaneous tissue disorders	306	0.02 %
Skin mass	Skin and subcutaneous tissue disorders	306	0.02 %
Haematemesis	Gastrointestinal disorders	304	0.02 %
Injection site oedema	General disorders and administration site conditions	304	0.02 %
Pneumonitis	Respiratory, thoracic and mediastinal disorders	303	0.02 %
Language disorder	Nervous system disorders	301	0.02 %
Multiple organ dysfunction syndrome	General disorders and administration site conditions	300	0.02 %
Irritable bowel syndrome	Gastrointestinal disorders	299	0.02 %
Liver disorder	Hepatobiliary disorders	299	0.02 %
Lip pain	Gastrointestinal disorders	298	0.02 %
Neuralgic amyotrophy	Nervous system disorders	298	0.02 %
Blindness unilateral	Eye disorders	297	0.02 %
Systemic lupus erythematosus	Musculoskeletal and connective tissue disorders	296	0.02 %
Acute respiratory failure	Respiratory, thoracic and mediastinal disorders	295	0.02 %
Gastric disorder	Gastrointestinal disorders	294	0.02 %
Nystagmus	Nervous system disorders	293	0.02 %
Pulmonary infarction	Respiratory, thoracic and mediastinal disorders	293	0.02 %
Bradyphrenia	Psychiatric disorders	291	0.02 %
Dermatitis bullous	Skin and subcutaneous tissue disorders	291	0.02 %
Blood creatinine increased	Investigations	290	0.02 %
Gamma-glutamyltransferase increased	Investigations	289	0.02 %
Limb mass	Musculoskeletal and connective tissue disorders	289	0.02 %
Nipple pain	Reproductive system and breast disorders	289	0.02 %
Skin haemorrhage	Skin and subcutaneous tissue disorders	289	0.02 %
Hypokalaemia	Metabolism and nutrition disorders	288	0.02 %
Vaccination site hypersensitivity	General disorders and administration site conditions	287	0.02 %
Chillblains	Injury, poisoning and procedural complications	286	0.02 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Faeces soft	Gastrointestinal disorders	286	0.02 %
Gingival swelling	Gastrointestinal disorders	285	0.02 %
Periorbital oedema	Eye disorders	285	0.02 %
Inflammatory marker increased	Investigations	284	0.02 %
Pneumonia aspiration	Infections and infestations	283	0.02 %
Facial discomfort	General disorders and administration site conditions	282	0.02 %
Secretion discharge	General disorders and administration site conditions	282	0.02 %
Suffocation feeling	Respiratory, thoracic and mediastinal disorders	282	0.02 %
Trismus	Musculoskeletal and connective tissue disorders	281	0.02 %
Myoclonus	Nervous system disorders	280	0.02 %
Dermatitis atopic	Skin and subcutaneous tissue disorders	279	0.02 %
Stridor	Respiratory, thoracic and mediastinal disorders	278	0.02 %
Application site swelling	General disorders and administration site conditions	277	0.02 %
Anaesthesia	Nervous system disorders	275	0.02 %
Muscle discomfort	Musculoskeletal and connective tissue disorders	275	0.02 %
Injury	Injury, poisoning and procedural complications	274	0.02 %
Lymphopenia	Blood and lymphatic system disorders	274	0.02 %
Sinus disorder	Respiratory, thoracic and mediastinal disorders	274	0.02 %
Ventricular fibrillation	Cardiac disorders	274	0.02 %
Anovulatory cycle	Endocrine disorders	273	0.02 %
Autoimmune thyroiditis	Endocrine disorders	273	0.02 %
Nuchal rigidity	Musculoskeletal and connective tissue disorders	272	0.02 %
Orthostatic hypotension	Vascular disorders	272	0.02 %
Rhabdomyolysis	Musculoskeletal and connective tissue disorders	271	0.02 %
Sense of oppression	General disorders and administration site conditions	271	0.02 %
Arthritis reactive	Musculoskeletal and connective tissue disorders	270	0.02 %
Choking sensation	Respiratory, thoracic and mediastinal disorders	270	0.02 %
Hangover	General disorders and administration site conditions	270	0.02 %
Hypogeausia	Nervous system disorders	270	0.02 %
Uterine pain	Reproductive system and breast disorders	270	0.02 %
Cystitis noninfective	Renal and urinary disorders	269	0.02 %
Shoulder injury related to vaccine administration	General disorders and administration site conditions	269	0.02 %
Supraventricular extrasystoles	Cardiac disorders	269	0.02 %
Food allergy	Immune system disorders	268	0.02 %
Ventricular tachycardia	Cardiac disorders	266	0.02 %
Abnormal withdrawal bleeding	Reproductive system and breast disorders	265	0.02 %
Cyst	General disorders and administration site conditions	265	0.02 %
Frequent bowel movements	Gastrointestinal disorders	265	0.02 %
Ear disorder	Ear and labyrinth disorders	263	0.02 %
Hemianaesthesia	Nervous system disorders	263	0.02 %
Thyroiditis subacute	Endocrine disorders	263	0.02 %
Labyrinthitis	Infections and infestations	262	0.02 %
Postural orthostatic tachycardia syndrome	Cardiac disorders	262	0.02 %
Dementia	Nervous system disorders	261	0.02 %
Haemorrhoids	Gastrointestinal disorders	261	0.02 %
Liver function test abnormal	Investigations	261	0.02 %
Wound	Injury, poisoning and procedural complications	261	0.02 %
Cardiomyopathy	Cardiac disorders	259	0.02 %
Nephrotic syndrome	Renal and urinary disorders	259	0.02 %
Pancreatitis	Gastrointestinal disorders	259	0.02 %
Cerebral ischaemia	Nervous system disorders	257	0.02 %
Lip pruritus	Gastrointestinal disorders	257	0.02 %
Rotator cuff syndrome	Musculoskeletal and connective tissue disorders	257	0.02 %
Leukocytosis	Blood and lymphatic system disorders	256	0.02 %
Renal disorder	Renal and urinary disorders	255	0.02 %
Vaccination site vesicles	General disorders and administration site conditions	255	0.02 %
Blood lactate dehydrogenase increased	Investigations	254	0.02 %
Incontinence	Renal and urinary disorders	254	0.02 %
Blindness transient	Eye disorders	253	0.02 %
Blood cholesterol increased	Investigations	251	0.02 %
Body temperature	Investigations	251	0.02 %
Hyponatraemia	Metabolism and nutrition disorders	250	0.02 %
Haemorrhage subcutaneous	Skin and subcutaneous tissue disorders	249	0.02 %
Tongue pruritus	Gastrointestinal disorders	249	0.02 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Generalised oedema	General disorders and administration site conditions	248	0.02 %
International normalised ratio increased	Investigations	248	0.02 %
Neurodermatitis	Skin and subcutaneous tissue disorders	248	0.02 %
Post herpetic neuralgia	Nervous system disorders	248	0.02 %
Vaccination site nodule	General disorders and administration site conditions	246	0.02 %
Diverticulitis	Infections and infestations	245	0.02 %
Gingivitis	Infections and infestations	245	0.02 %
Ovarian cyst	Reproductive system and breast disorders	243	0.02 %
Blood thyroid stimulating hormone increased	Investigations	241	0.02 %
Hypophagia	Metabolism and nutrition disorders	241	0.02 %
Miliaria	Skin and subcutaneous tissue disorders	241	0.02 %
Vein disorder	Vascular disorders	241	0.02 %
Muscle disorder	Musculoskeletal and connective tissue disorders	240	0.02 %
Diarrhoea haemorrhagic	Gastrointestinal disorders	239	0.02 %
Menopausal symptoms	Reproductive system and breast disorders	238	0.02 %
Pharyngeal hypoesthesia	Respiratory, thoracic and mediastinal disorders	238	0.02 %
Platelet count increased	Investigations	237	0.02 %
Ear pruritus	Ear and labyrinth disorders	236	0.02 %
Muscle contracture	Musculoskeletal and connective tissue disorders	236	0.02 %
Myelitis transverse	Nervous system disorders	236	0.02 %
Neutropenia	Blood and lymphatic system disorders	236	0.02 %
Proteinuria	Renal and urinary disorders	236	0.02 %
Dyspnoea at rest	Respiratory, thoracic and mediastinal disorders	235	0.02 %
Giant cell arteritis	Vascular disorders	235	0.02 %
Internal haemorrhage	Vascular disorders	235	0.02 %
Respiratory symptom	Respiratory, thoracic and mediastinal disorders	235	0.02 %
Acute respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	234	0.02 %
Cardiac failure acute	Cardiac disorders	234	0.02 %
Vaccination site joint erythema	General disorders and administration site conditions	234	0.02 %
Febrile convulsion	Nervous system disorders	233	0.02 %
Laryngitis	Infections and infestations	233	0.02 %
Mydriasis	Eye disorders	233	0.02 %
Synovial cyst	Musculoskeletal and connective tissue disorders	232	0.02 %
Coronary artery disease	Cardiac disorders	231	0.02 %
Mouth haemorrhage	Gastrointestinal disorders	231	0.02 %
Uterine haemorrhage	Reproductive system and breast disorders	231	0.02 %
Cerebral venous thrombosis	Nervous system disorders	230	0.02 %
Hepatitis	Hepatobiliary disorders	230	0.02 %
Joint effusion	Musculoskeletal and connective tissue disorders	229	0.02 %
Asthmatic crisis	Respiratory, thoracic and mediastinal disorders	228	0.02 %
Cardiac failure congestive	Cardiac disorders	228	0.02 %
Septic shock	Infections and infestations	227	0.02 %
Euphoric mood	Psychiatric disorders	226	0.02 %
Heart rate	Investigations	226	0.02 %
Hepatic cytolysis	Hepatobiliary disorders	226	0.02 %
Leukopenia	Blood and lymphatic system disorders	226	0.02 %
Myocardial ischaemia	Cardiac disorders	226	0.02 %
Ophthalmic migraine	Nervous system disorders	226	0.02 %
Urticaria chronic	Skin and subcutaneous tissue disorders	226	0.02 %
Cutaneous vasculitis	Skin and subcutaneous tissue disorders	225	0.02 %
Oral disorder	Gastrointestinal disorders	225	0.02 %
Scar	Injury, poisoning and procedural complications	225	0.02 %
Hepatic pain	Hepatobiliary disorders	224	0.02 %
Aggression	Psychiatric disorders	223	0.02 %
Rash morbilliform	Skin and subcutaneous tissue disorders	223	0.02 %
Blood test abnormal	Investigations	222	0.02 %
Lip dry	Gastrointestinal disorders	222	0.02 %
Muscle atrophy	Musculoskeletal and connective tissue disorders	222	0.02 %
Nephrolithiasis	Renal and urinary disorders	221	0.02 %
Vaccination site joint swelling	General disorders and administration site conditions	220	0.02 %
Choking	Respiratory, thoracic and mediastinal disorders	219	0.02 %
Eye oedema	Eye disorders	219	0.02 %
Neutrophil count increased	Investigations	219	0.02 %
Scab	Skin and subcutaneous tissue disorders	219	0.02 %
Diabetes mellitus inadequate control	Metabolism and nutrition disorders	217	0.02 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Furuncle	Infections and infestations	217	0.02 %
Abscess	Infections and infestations	216	0.02 %
Increased appetite	Metabolism and nutrition disorders	216	0.02 %
Mitral valve incompetence	Cardiac disorders	216	0.02 %
Polyuria	Renal and urinary disorders	216	0.02 %
Troponin I increased	Investigations	215	0.02 %
Exposure to SARS-CoV-2	Injury, poisoning and procedural complications	214	0.02 %
Medication error	Injury, poisoning and procedural complications	214	0.02 %
Thyroid disorder	Endocrine disorders	214	0.02 %
Transaminases increased	Investigations	214	0.02 %
Conjunctival hyperaemia	Eye disorders	213	0.02 %
Post viral fatigue syndrome	Infections and infestations	213	0.02 %
Respiratory tract infection	Infections and infestations	213	0.02 %
Erythema of eyelid	Eye disorders	212	0.02 %
Muscle swelling	Musculoskeletal and connective tissue disorders	212	0.02 %
Vitreous detachment	Eye disorders	212	0.02 %
Carpal tunnel syndrome	Nervous system disorders	211	0.02 %
Ear congestion	Ear and labyrinth disorders	211	0.02 %
Pemphigoid	Skin and subcutaneous tissue disorders	210	0.02 %
Peripheral venous disease	Vascular disorders	210	0.02 %
Rash pustular	Infections and infestations	210	0.02 %
Auditory disorder	Ear and labyrinth disorders	209	0.02 %
Psoriatic arthropathy	Musculoskeletal and connective tissue disorders	209	0.02 %
Temperature intolerance	General disorders and administration site conditions	209	0.02 %
Arteriosclerosis	Vascular disorders	208	0.02 %
Status epilepticus	Nervous system disorders	208	0.02 %
Uterine spasm	Reproductive system and breast disorders	208	0.02 %
Nerve compression	Nervous system disorders	207	0.02 %
Post-acute COVID-19 syndrome	Infections and infestations	207	0.02 %
Abnormal sensation in eye	Eye disorders	206	0.02 %
Breast inflammation	Reproductive system and breast disorders	205	0.02 %
Eye discharge	Eye disorders	205	0.02 %
Goitre	Endocrine disorders	205	0.02 %
Poor peripheral circulation	Vascular disorders	205	0.02 %
Thyroiditis	Endocrine disorders	205	0.02 %
Cardiogenic shock	Cardiac disorders	204	0.02 %
Torticollis	Musculoskeletal and connective tissue disorders	204	0.02 %
Anger	Psychiatric disorders	203	0.02 %
Fungal infection	Infections and infestations	203	0.02 %
Glossitis	Gastrointestinal disorders	203	0.02 %
Livedo reticularis	Skin and subcutaneous tissue disorders	203	0.02 %
Scratch	Injury, poisoning and procedural complications	203	0.02 %
Type I hypersensitivity	Immune system disorders	203	0.02 %
Deafness neurosensory	Ear and labyrinth disorders	202	0.01 %
Neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	202	0.01 %
Type 1 diabetes mellitus	Metabolism and nutrition disorders	202	0.01 %
Lichen planus	Skin and subcutaneous tissue disorders	200	0.01 %
Skin tightness	Skin and subcutaneous tissue disorders	200	0.01 %
Accidental exposure to product	Injury, poisoning and procedural complications	199	0.01 %
Hallucination, visual	Psychiatric disorders	199	0.01 %
Rhinitis allergic	Respiratory, thoracic and mediastinal disorders	199	0.01 %
Anaphylactoid reaction	Immune system disorders	197	0.01 %
Application site erythema	General disorders and administration site conditions	197	0.01 %
Bradykinesia	Nervous system disorders	197	0.01 %
Brain oedema	Nervous system disorders	197	0.01 %
Increased tendency to bruise	Blood and lymphatic system disorders	197	0.01 %
Near death experience	Psychiatric disorders	197	0.01 %
Lip blister	Gastrointestinal disorders	196	0.01 %
Motion sickness	Ear and labyrinth disorders	195	0.01 %
Myasthenia gravis	Nervous system disorders	195	0.01 %
Psychomotor hyperactivity	Nervous system disorders	195	0.01 %
Ischaemia	Vascular disorders	194	0.01 %
Obstructive airways disorder	Respiratory, thoracic and mediastinal disorders	194	0.01 %
Ankylosing spondylitis	Musculoskeletal and connective tissue disorders	193	0.01 %
Spontaneous haematoma	Blood and lymphatic system disorders	193	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vaccination site cellulitis	Infections and infestations	193	0.01 %
Abnormal behaviour	Psychiatric disorders	192	0.01 %
Diplegia	Nervous system disorders	192	0.01 %
Infectious mononucleosis	Infections and infestations	192	0.01 %
Intervertebral disc protrusion	Musculoskeletal and connective tissue disorders	192	0.01 %
Retinal artery occlusion	Eye disorders	192	0.01 %
Walking disability	Social circumstances	192	0.01 %
Gastrointestinal haemorrhage	Gastrointestinal disorders	191	0.01 %
Retinal detachment	Eye disorders	191	0.01 %
Vulvovaginal pain	Reproductive system and breast disorders	191	0.01 %
Injection site warmth	General disorders and administration site conditions	190	0.01 %
Autonomic nervous system imbalance	Nervous system disorders	189	0.01 %
Pharyngeal erythema	Respiratory, thoracic and mediastinal disorders	189	0.01 %
Piloerection	Skin and subcutaneous tissue disorders	189	0.01 %
Splenomegaly	Blood and lymphatic system disorders	189	0.01 %
Upper respiratory tract infection	Infections and infestations	189	0.01 %
Hordeolum	Infections and infestations	188	0.01 %
Hyposmia	Nervous system disorders	187	0.01 %
Meningitis	Infections and infestations	187	0.01 %
Peripheral ischaemia	Vascular disorders	187	0.01 %
Sarcoidosis	Immune system disorders	186	0.01 %
Herpes zoster oticus	Infections and infestations	185	0.01 %
Injection site induration	General disorders and administration site conditions	185	0.01 %
Red blood cell count decreased	Investigations	184	0.01 %
Vestibular disorder	Ear and labyrinth disorders	184	0.01 %
Yawning	Respiratory, thoracic and mediastinal disorders	184	0.01 %
Pulmonary congestion	Respiratory, thoracic and mediastinal disorders	183	0.01 %
Blood potassium decreased	Investigations	182	0.01 %
Unevaluable event	General disorders and administration site conditions	182	0.01 %
Lymphocyte count decreased	Investigations	181	0.01 %
Ovulation delayed	Endocrine disorders	181	0.01 %
Premature baby	Pregnancy, puerperium and perinatal conditions	181	0.01 %
Vomiting projectile	Gastrointestinal disorders	181	0.01 %
Anal incontinence	Gastrointestinal disorders	179	0.01 %
Cheilitis	Gastrointestinal disorders	179	0.01 %
Non-cardiac chest pain	General disorders and administration site conditions	179	0.01 %
Noninfective gingivitis	Gastrointestinal disorders	179	0.01 %
Pyelonephritis	Infections and infestations	179	0.01 %
Troponin T increased	Investigations	179	0.01 %
Injection site hypoesthesia	General disorders and administration site conditions	178	0.01 %
Dermatitis contact	Skin and subcutaneous tissue disorders	177	0.01 %
Ejection fraction decreased	Investigations	176	0.01 %
Eye injury	Injury, poisoning and procedural complications	176	0.01 %
Tachyarrhythmia	Cardiac disorders	176	0.01 %
Rosacea	Skin and subcutaneous tissue disorders	174	0.01 %
Aura	Nervous system disorders	173	0.01 %
Carditis	Cardiac disorders	173	0.01 %
Cholelithiasis	Hepatobiliary disorders	173	0.01 %
Haemorrhagic stroke	Nervous system disorders	173	0.01 %
Meniere's disease	Ear and labyrinth disorders	173	0.01 %
Vulvovaginal mycotic infection	Infections and infestations	173	0.01 %
Liver function test increased	Investigations	172	0.01 %
Nasal dryness	Respiratory, thoracic and mediastinal disorders	172	0.01 %
Blepharitis	Eye disorders	171	0.01 %
Energy increased	General disorders and administration site conditions	171	0.01 %
Rhinalgia	Respiratory, thoracic and mediastinal disorders	171	0.01 %
Tongue discolouration	Gastrointestinal disorders	171	0.01 %
Varicella	Infections and infestations	171	0.01 %
Skin ulcer	Skin and subcutaneous tissue disorders	170	0.01 %
Tendon disorder	Musculoskeletal and connective tissue disorders	170	0.01 %
Demyelination	Nervous system disorders	169	0.01 %
Glomerular filtration rate decreased	Investigations	169	0.01 %
Joint injury	Injury, poisoning and procedural complications	169	0.01 %
Lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	169	0.01 %
Palatal oedema	Gastrointestinal disorders	169	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Road traffic accident	Injury, poisoning and procedural complications	168	0.01 %
Cardiac fibrillation	Cardiac disorders	167	0.01 %
Skin odour abnormal	Skin and subcutaneous tissue disorders	167	0.01 %
Skin sensitisation	Skin and subcutaneous tissue disorders	167	0.01 %
Catarrh	Respiratory, thoracic and mediastinal disorders	166	0.01 %
Product quality issue	Product issues	166	0.01 %
Sensory level abnormal	Investigations	166	0.01 %
Breast engorgement	Reproductive system and breast disorders	165	0.01 %
Lymph node palpable	Investigations	165	0.01 %
Vitiligo	Skin and subcutaneous tissue disorders	165	0.01 %
Blood bilirubin increased	Investigations	164	0.01 %
Hiccups	Respiratory, thoracic and mediastinal disorders	164	0.01 %
Pigmentation disorder	Skin and subcutaneous tissue disorders	164	0.01 %
Eye infection	Infections and infestations	162	0.01 %
Facial spasm	Nervous system disorders	162	0.01 %
Herpes zoster reactivation	Infections and infestations	162	0.01 %
Apnoea	Respiratory, thoracic and mediastinal disorders	161	0.01 %
Kidney infection	Infections and infestations	161	0.01 %
Portal vein thrombosis	Hepatobiliary disorders	161	0.01 %
Respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	161	0.01 %
Skin laceration	Injury, poisoning and procedural complications	161	0.01 %
Blood pressure diastolic increased	Investigations	160	0.01 %
Appetite disorder	Metabolism and nutrition disorders	159	0.01 %
Bacterial infection	Infections and infestations	159	0.01 %
Candida infection	Infections and infestations	159	0.01 %
Fine motor skill dysfunction	Nervous system disorders	159	0.01 %
Rales	Respiratory, thoracic and mediastinal disorders	159	0.01 %
Bundle branch block right	Cardiac disorders	158	0.01 %
Localised infection	Infections and infestations	158	0.01 %
Skin discomfort	Skin and subcutaneous tissue disorders	158	0.01 %
Allodynia	Nervous system disorders	157	0.01 %
Eyelid pain	Eye disorders	157	0.01 %
Sick leave	Social circumstances	157	0.01 %
Hyperaemia	Vascular disorders	156	0.01 %
Asphyxia	Respiratory, thoracic and mediastinal disorders	155	0.01 %
Connective tissue disorder	Musculoskeletal and connective tissue disorders	155	0.01 %
Product dose omission issue	Injury, poisoning and procedural complications	155	0.01 %
Product leakage	Product issues	155	0.01 %
Bladder pain	Renal and urinary disorders	154	0.01 %
Brain injury	Nervous system disorders	154	0.01 %
Epigastric discomfort	Gastrointestinal disorders	154	0.01 %
Sleep deficit	Nervous system disorders	154	0.01 %
Increased upper airway secretion	Respiratory, thoracic and mediastinal disorders	153	0.01 %
Iridocyclitis	Eye disorders	153	0.01 %
Petit mal epilepsy	Nervous system disorders	153	0.01 %
Affect lability	Psychiatric disorders	152	0.01 %
Autoimmune hepatitis	Hepatobiliary disorders	151	0.01 %
Cardiac murmur	Investigations	151	0.01 %
Adverse event following immunisation	Injury, poisoning and procedural complications	150	0.01 %
Muscle spasticity	Nervous system disorders	150	0.01 %
Orthopnoea	Respiratory, thoracic and mediastinal disorders	150	0.01 %
Bowel movement irregularity	Gastrointestinal disorders	149	0.01 %
Cataract	Eye disorders	149	0.01 %
Herpes ophthalmic	Infections and infestations	149	0.01 %
Hypotonic-hyporesponsive episode	Nervous system disorders	149	0.01 %
Joint lock	Musculoskeletal and connective tissue disorders	149	0.01 %
Pancytopenia	Blood and lymphatic system disorders	149	0.01 %
Sleep apnoea syndrome	Respiratory, thoracic and mediastinal disorders	149	0.01 %
Tongue ulceration	Gastrointestinal disorders	149	0.01 %
Concussion	Injury, poisoning and procedural complications	148	0.01 %
Infarction	Vascular disorders	148	0.01 %
Mastication disorder	Musculoskeletal and connective tissue disorders	148	0.01 %
Oral candidiasis	Infections and infestations	148	0.01 %
Sweating fever	Infections and infestations	148	0.01 %
Angiopathy	Vascular disorders	147	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	147	0.01 %
Foetal death	Pregnancy, puerperium and perinatal conditions	147	0.01 %
Henoch-Schonlein purpura	Skin and subcutaneous tissue disorders	147	0.01 %
Left ventricular dysfunction	Cardiac disorders	147	0.01 %
Peripheral artery thrombosis	Vascular disorders	147	0.01 %
Tic	Psychiatric disorders	147	0.01 %
Blood iron decreased	Investigations	146	0.01 %
Blood pressure diastolic decreased	Investigations	146	0.01 %
Laryngeal discomfort	Respiratory, thoracic and mediastinal disorders	146	0.01 %
Ulcer	General disorders and administration site conditions	146	0.01 %
Vaccination site irritation	General disorders and administration site conditions	146	0.01 %
Blood glucose abnormal	Investigations	145	0.01 %
Eyelids pruritus	Eye disorders	145	0.01 %
Feeling of despair	Psychiatric disorders	145	0.01 %
Vaccination site infection	Infections and infestations	145	0.01 %
Atrioventricular block	Cardiac disorders	144	0.01 %
Illusion	Psychiatric disorders	144	0.01 %
Melaena	Gastrointestinal disorders	144	0.01 %
Serum ferritin increased	Investigations	144	0.01 %
Blood urea increased	Investigations	143	0.01 %
Facial asymmetry	Musculoskeletal and connective tissue disorders	143	0.01 %
Immunodeficiency	Immune system disorders	143	0.01 %
Nasal oedema	Respiratory, thoracic and mediastinal disorders	143	0.01 %
Sedation	Nervous system disorders	143	0.01 %
Blood glucose fluctuation	Investigations	142	0.01 %
Eosinophilia	Blood and lymphatic system disorders	142	0.01 %
Hyperleukocytosis	Blood and lymphatic system disorders	142	0.01 %
Pneumothorax	Respiratory, thoracic and mediastinal disorders	142	0.01 %
Subdural haematoma	Injury, poisoning and procedural complications	142	0.01 %
Upper respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	142	0.01 %
Arthropod bite	Injury, poisoning and procedural complications	141	0.01 %
Dissociation	Psychiatric disorders	141	0.01 %
Dysphemia	Psychiatric disorders	141	0.01 %
Lymphangitis	Infections and infestations	141	0.01 %
Menopause	Social circumstances	141	0.01 %
Optic ischaemic neuropathy	Eye disorders	141	0.01 %
Retinal vein thrombosis	Eye disorders	141	0.01 %
Acute disseminated encephalomyelitis	Nervous system disorders	140	0.01 %
Cervicobrachial syndrome	Nervous system disorders	139	0.01 %
Haematocrit decreased	Investigations	139	0.01 %
Partial seizures	Nervous system disorders	139	0.01 %
Psychotic disorder	Psychiatric disorders	139	0.01 %
Acute pulmonary oedema	Respiratory, thoracic and mediastinal disorders	138	0.01 %
Application site reaction	General disorders and administration site conditions	138	0.01 %
Injection site mass	General disorders and administration site conditions	138	0.01 %
Dizziness exertional	Nervous system disorders	137	0.01 %
Immobile	Social circumstances	137	0.01 %
Joint noise	Musculoskeletal and connective tissue disorders	137	0.01 %
Mechanical urticaria	Skin and subcutaneous tissue disorders	137	0.01 %
Sinus bradycardia	Cardiac disorders	137	0.01 %
Ascites	Gastrointestinal disorders	136	0.01 %
Blood blister	Skin and subcutaneous tissue disorders	136	0.01 %
Blood fibrinogen increased	Investigations	136	0.01 %
Decreased activity	General disorders and administration site conditions	136	0.01 %
Encephalopathy	Nervous system disorders	136	0.01 %
Gastrointestinal sounds abnormal	Gastrointestinal disorders	136	0.01 %
Intracranial pressure increased	Nervous system disorders	136	0.01 %
Pharyngeal inflammation	Respiratory, thoracic and mediastinal disorders	136	0.01 %
Areflexia	Nervous system disorders	135	0.01 %
Embolic stroke	Nervous system disorders	135	0.01 %
Hepatic steatosis	Hepatobiliary disorders	135	0.01 %
Radiculopathy	Nervous system disorders	135	0.01 %
Tongue blistering	Gastrointestinal disorders	135	0.01 %
Hyperaesthesia teeth	Gastrointestinal disorders	134	0.01 %
Iron deficiency	Metabolism and nutrition disorders	134	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Papilloedema	Eye disorders	134	0.01 %
Vaccination site injury	General disorders and administration site conditions	134	0.01 %
Aortic dissection	Vascular disorders	133	0.01 %
Haemorrhoids thrombosed	Gastrointestinal disorders	133	0.01 %
Laryngospasm	Respiratory, thoracic and mediastinal disorders	133	0.01 %
Libido decreased	Psychiatric disorders	133	0.01 %
Ligament sprain	Injury, poisoning and procedural complications	133	0.01 %
Parotitis	Infections and infestations	133	0.01 %
Retinal haemorrhage	Eye disorders	133	0.01 %
Blood alkaline phosphatase increased	Investigations	132	0.01 %
Cerebellar infarction	Nervous system disorders	132	0.01 %
Cerebral disorder	Nervous system disorders	132	0.01 %
Intraocular pressure increased	Investigations	132	0.01 %
Systemic inflammatory response syndrome	General disorders and administration site conditions	132	0.01 %
Tenosynovitis	Musculoskeletal and connective tissue disorders	132	0.01 %
Brain natriuretic peptide increased	Investigations	131	0.01 %
N-terminal prohormone brain natriuretic peptide increased	Investigations	131	0.01 %
Temporomandibular joint syndrome	Musculoskeletal and connective tissue disorders	131	0.01 %
Myocardial necrosis marker increased	Investigations	130	0.01 %
Nasal pruritus	Respiratory, thoracic and mediastinal disorders	130	0.01 %
Skin abrasion	Injury, poisoning and procedural complications	130	0.01 %
Adverse reaction	General disorders and administration site conditions	129	0.01 %
Sjogren's syndrome	Musculoskeletal and connective tissue disorders	129	0.01 %
Slow speech	Nervous system disorders	129	0.01 %
Toxic skin eruption	Skin and subcutaneous tissue disorders	129	0.01 %
Urine odour abnormal	Renal and urinary disorders	129	0.01 %
Congestive cardiomyopathy	Cardiac disorders	128	0.01 %
Ischaemic cerebral infarction	Nervous system disorders	128	0.01 %
Needle issue	Product issues	128	0.01 %
Abdominal tenderness	Gastrointestinal disorders	126	0.01 %
Bone swelling	Musculoskeletal and connective tissue disorders	126	0.01 %
Disease progression	General disorders and administration site conditions	126	0.01 %
Epicondylitis	Injury, poisoning and procedural complications	126	0.01 %
Hypertonia	Nervous system disorders	126	0.01 %
Impaired healing	General disorders and administration site conditions	126	0.01 %
Pulmonary hypertension	Respiratory, thoracic and mediastinal disorders	126	0.01 %
Bacille Calmette-Guerin scar reactivation	Immune system disorders	125	0.01 %
Blood sodium decreased	Investigations	125	0.01 %
Breath sounds abnormal	Investigations	125	0.01 %
Dermatitis acneiform	Skin and subcutaneous tissue disorders	125	0.01 %
Fear of death	Psychiatric disorders	125	0.01 %
Inflammatory pain	General disorders and administration site conditions	125	0.01 %
Atrioventricular block complete	Cardiac disorders	124	0.01 %
Drooling	Nervous system disorders	124	0.01 %
Foetal growth restriction	Pregnancy, puerperium and perinatal conditions	124	0.01 %
Puncture site pain	General disorders and administration site conditions	124	0.01 %
Tearfulness	Psychiatric disorders	124	0.01 %
VIIth nerve paralysis	Nervous system disorders	124	0.01 %
Autoimmune haemolytic anaemia	Blood and lymphatic system disorders	123	0.01 %
Capillary fragility	Vascular disorders	123	0.01 %
Chronic kidney disease	Renal and urinary disorders	123	0.01 %
Coronary artery thrombosis	Cardiac disorders	123	0.01 %
Injection site rash	General disorders and administration site conditions	123	0.01 %
Intestinal ischaemia	Gastrointestinal disorders	123	0.01 %
Tongue coated	Gastrointestinal disorders	123	0.01 %
Yellow skin	Skin and subcutaneous tissue disorders	123	0.01 %
Bundle branch block left	Cardiac disorders	122	0.01 %
Neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	122	0.01 %
Panic disorder	Psychiatric disorders	122	0.01 %
Soft tissue swelling	Musculoskeletal and connective tissue disorders	122	0.01 %
Thermal burn	Injury, poisoning and procedural complications	122	0.01 %
Tunnel vision	Nervous system disorders	122	0.01 %
Upper-airway cough syndrome	Respiratory, thoracic and mediastinal disorders	122	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vitamin D deficiency	Metabolism and nutrition disorders	122	0.01 %
Vulvovaginal candidiasis	Infections and infestations	122	0.01 %
Conversion disorder	Psychiatric disorders	121	0.01 %
Food intolerance	Metabolism and nutrition disorders	121	0.01 %
Lung infiltration	Respiratory, thoracic and mediastinal disorders	121	0.01 %
Mesenteric vein thrombosis	Gastrointestinal disorders	121	0.01 %
Nasal obstruction	Respiratory, thoracic and mediastinal disorders	121	0.01 %
Neutrophil count decreased	Investigations	121	0.01 %
Ophthalmic vein thrombosis	Eye disorders	121	0.01 %
Polydipsia	Metabolism and nutrition disorders	121	0.01 %
Adverse drug reaction	General disorders and administration site conditions	120	0.01 %
Hyporeflexia	Nervous system disorders	120	0.01 %
Occipital neuralgia	Nervous system disorders	120	0.01 %
Renal colic	Renal and urinary disorders	120	0.01 %
Arterial occlusive disease	Vascular disorders	119	0.01 %
Clumsiness	Nervous system disorders	119	0.01 %
Face injury	Injury, poisoning and procedural complications	119	0.01 %
Gastrointestinal inflammation	Gastrointestinal disorders	119	0.01 %
Infection susceptibility increased	Infections and infestations	119	0.01 %
Macule	Skin and subcutaneous tissue disorders	119	0.01 %
Abnormal loss of weight	Metabolism and nutrition disorders	118	0.01 %
Defaecation urgency	Gastrointestinal disorders	118	0.01 %
Functional gastrointestinal disorder	Gastrointestinal disorders	118	0.01 %
Hepatomegaly	Hepatobiliary disorders	118	0.01 %
Hypoesthesia eye	Eye disorders	118	0.01 %
Low density lipoprotein increased	Investigations	118	0.01 %
Muscle injury	Injury, poisoning and procedural complications	118	0.01 %
Skin fissures	Skin and subcutaneous tissue disorders	118	0.01 %
Ventricular hypokinesia	Cardiac disorders	118	0.01 %
Anxiety disorder	Psychiatric disorders	117	0.01 %
Atelectasis	Respiratory, thoracic and mediastinal disorders	117	0.01 %
Eosinophil count increased	Investigations	117	0.01 %
Incomplete course of vaccination	Injury, poisoning and procedural complications	117	0.01 %
Stupor	Nervous system disorders	117	0.01 %
Transient global amnesia	Nervous system disorders	117	0.01 %
Frustration tolerance decreased	Psychiatric disorders	116	0.01 %
Lactation disorder	Reproductive system and breast disorders	116	0.01 %
Meningitis aseptic	Infections and infestations	116	0.01 %
Sleep disorder due to general medical condition, insomnia type	Psychiatric disorders	116	0.01 %
Somatic symptom disorder	Psychiatric disorders	116	0.01 %
Stress cardiomyopathy	Cardiac disorders	116	0.01 %
Breast cyst	Reproductive system and breast disorders	115	0.01 %
Cholestasis	Hepatobiliary disorders	115	0.01 %
Delusion	Psychiatric disorders	115	0.01 %
Epstein-Barr virus infection reactivation	Infections and infestations	115	0.01 %
Gastroenteritis viral	Infections and infestations	115	0.01 %
Genital haemorrhage	Reproductive system and breast disorders	115	0.01 %
Tongue erythema	Gastrointestinal disorders	115	0.01 %
Trigeminal nerve disorder	Nervous system disorders	115	0.01 %
Abortion missed	Pregnancy, puerperium and perinatal conditions	114	0.01 %
Exposure via skin contact	Injury, poisoning and procedural complications	114	0.01 %
Eyelid irritation	Eye disorders	114	0.01 %
Type IV hypersensitivity reaction	Immune system disorders	114	0.01 %
Vaccination site hyperaesthesia	General disorders and administration site conditions	114	0.01 %
Abdominal rigidity	Gastrointestinal disorders	113	0.01 %
Breast oedema	Reproductive system and breast disorders	113	0.01 %
Intestinal obstruction	Gastrointestinal disorders	113	0.01 %
Lip disorder	Gastrointestinal disorders	113	0.01 %
Synovitis	Musculoskeletal and connective tissue disorders	113	0.01 %
Glycosylated haemoglobin increased	Investigations	112	0.01 %
Endocarditis	Infections and infestations	111	0.01 %
Myocardial injury	Cardiac disorders	111	0.01 %
Palatal swelling	Gastrointestinal disorders	111	0.01 %
Vaccination site abscess	Infections and infestations	111	0.01 %
Enlarged uvula	Gastrointestinal disorders	110	0.01 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Eye contusion	Injury, poisoning and procedural complications	110	0.01 %
Eyelid disorder	Eye disorders	110	0.01 %
Tongue dry	Gastrointestinal disorders	110	0.01 %
Antibody test abnormal	Investigations	109	0.01 %
Antinuclear antibody positive	Investigations	109	0.01 %
Epstein-Barr virus infection	Infections and infestations	109	0.01 %
Foreign body sensation in eyes	Eye disorders	109	0.01 %
Incoherent	Nervous system disorders	109	0.01 %
Phlebitis superficial	Vascular disorders	109	0.01 %
Procedural complication	Injury, poisoning and procedural complications	109	0.01 %
Skin plaque	Skin and subcutaneous tissue disorders	109	0.01 %
Small fibre neuropathy	Nervous system disorders	109	0.01 %
Sunburn	Injury, poisoning and procedural complications	109	0.01 %
Thrombocytopenic purpura	Blood and lymphatic system disorders	109	0.01 %
Blood creatine phosphokinase MB increased	Investigations	108	0.01 %
Decreased immune responsiveness	Immune system disorders	108	0.01 %
Disseminated intravascular coagulation	Blood and lymphatic system disorders	108	0.01 %
Thyroid mass	Endocrine disorders	108	0.01 %
Tooth disorder	Gastrointestinal disorders	108	0.01 %
Tricuspid valve incompetence	Cardiac disorders	108	0.01 %
Trigger finger	Musculoskeletal and connective tissue disorders	108	0.01 %
Adverse event	General disorders and administration site conditions	107	0.01 %
Blood pressure systolic decreased	Investigations	107	0.01 %
Dyshidrotic eczema	Skin and subcutaneous tissue disorders	107	0.01 %
Folliculitis	Infections and infestations	107	0.01 %
Left ventricular hypertrophy	Cardiac disorders	107	0.01 %
Lyme disease	Infections and infestations	107	0.01 %
Macular oedema	Eye disorders	107	0.01 %
Paraparesis	Nervous system disorders	107	0.01 %
Pneumonia bacterial	Infections and infestations	107	0.01 %
Respiratory rate decreased	Investigations	107	0.01 %
Sudden cardiac death	General disorders and administration site conditions	107	0.01 %
Syringe issue	Product issues	107	0.01 %
Coronary artery occlusion	Cardiac disorders	106	0.01 %
Dyslalia	Nervous system disorders	106	0.01 %
Hepatitis acute	Hepatobiliary disorders	106	0.01 %
Blood disorder	Blood and lymphatic system disorders	105	0.01 %
Cervical radiculopathy	Nervous system disorders	105	0.01 %
Derealisation	Psychiatric disorders	105	0.01 %
Hallucination, auditory	Psychiatric disorders	105	0.01 %
Parkinson's disease	Nervous system disorders	105	0.01 %
Peripheral circulatory failure	Vascular disorders	105	0.01 %
Sacral pain	Musculoskeletal and connective tissue disorders	105	0.01 %
Spinal osteoarthritis	Musculoskeletal and connective tissue disorders	105	0.01 %
Brain stem infarction	Nervous system disorders	104	0.01 %
Cerebrovascular disorder	Nervous system disorders	104	0.01 %
Full blood count abnormal	Investigations	104	0.01 %
Injection site inflammation	General disorders and administration site conditions	104	0.01 %
Parotid gland enlargement	Gastrointestinal disorders	104	0.01 %
Sitting disability	Social circumstances	104	0.01 %
Skin infection	Infections and infestations	104	0.01 %
Tetany	Metabolism and nutrition disorders	104	0.01 %
Varicella zoster virus infection	Infections and infestations	104	0.01 %
Facial nerve disorder	Nervous system disorders	103	0.01 %
Glaucoma	Eye disorders	103	0.01 %
Iritis	Eye disorders	103	0.01 %
Loss of libido	Psychiatric disorders	103	0.01 %
Mucous stools	Gastrointestinal disorders	103	0.01 %
Ocular vascular disorder	Eye disorders	103	0.01 %
Peripheral sensory neuropathy	Nervous system disorders	103	0.01 %
Urine abnormality	Renal and urinary disorders	103	0.01 %
Urine output decreased	Investigations	103	0.01 %
Blood thyroid stimulating hormone decreased	Investigations	102	0.01 %
Enteritis	Gastrointestinal disorders	102	0.01 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Iron deficiency anaemia	Blood and lymphatic system disorders	102	0.01 %
Loss of control of legs	General disorders and administration site conditions	102	0.01 %
Oedema mouth	Gastrointestinal disorders	102	0.01 %
Reaction to excipient	Immune system disorders	102	0.01 %
Tonic convulsion	Nervous system disorders	102	0.01 %
Coronary artery stenosis	Cardiac disorders	101	0.01 %
Joint warmth	Musculoskeletal and connective tissue disorders	101	0.01 %
Liquid product physical issue	Product issues	101	0.01 %
Liver injury	Hepatobiliary disorders	101	0.01 %
Monocyte count increased	Investigations	101	0.01 %
Palmar erythema	Skin and subcutaneous tissue disorders	101	0.01 %
Pulmonary mass	Respiratory, thoracic and mediastinal disorders	101	0.01 %
Abnormal uterine bleeding	Reproductive system and breast disorders	100	0.01 %
Anaesthesia oral	Gastrointestinal disorders	100	0.01 %
Chapped lips	Gastrointestinal disorders	100	0.01 %
Oral mucosal eruption	Gastrointestinal disorders	100	0.01 %
Cardiac tamponade	Cardiac disorders	99	0.01 %
Diaphragmalgia	Respiratory, thoracic and mediastinal disorders	99	0.01 %
Oral mucosal erythema	Gastrointestinal disorders	99	0.01 %
Pre-existing condition improved	General disorders and administration site conditions	99	0.01 %
Prostatitis	Reproductive system and breast disorders	99	0.01 %
Aspiration	Respiratory, thoracic and mediastinal disorders	98	0.01 %
Pelvic venous thrombosis	Vascular disorders	98	0.01 %
Type 2 diabetes mellitus	Metabolism and nutrition disorders	98	0.01 %
Biliary colic	Hepatobiliary disorders	97	0.01 %
Bladder disorder	Renal and urinary disorders	97	0.01 %
CSF protein increased	Investigations	97	0.01 %
Food aversion	Metabolism and nutrition disorders	97	0.01 %
Genital pain	Reproductive system and breast disorders	97	0.01 %
Hepatic failure	Hepatobiliary disorders	97	0.01 %
Nephritis	Renal and urinary disorders	97	0.01 %
Peroneal nerve palsy	Nervous system disorders	97	0.01 %
Rib fracture	Injury, poisoning and procedural complications	97	0.01 %
SARS-CoV-2 antibody test positive	Investigations	97	0.01 %
Sinus arrhythmia	Cardiac disorders	97	0.01 %
Thrombotic thrombocytopenic purpura	Blood and lymphatic system disorders	97	0.01 %
Back disorder	Musculoskeletal and connective tissue disorders	96	0.01 %
Colitis ischaemic	Gastrointestinal disorders	96	0.01 %
Ovulation disorder	Reproductive system and breast disorders	96	0.01 %
Strabismus	Eye disorders	96	0.01 %
Subclavian vein thrombosis	Vascular disorders	96	0.01 %
Tongue biting	Nervous system disorders	96	0.01 %
Aneurysm	Vascular disorders	95	0.01 %
Complex regional pain syndrome	Nervous system disorders	95	0.01 %
Emphysema	Respiratory, thoracic and mediastinal disorders	95	0.01 %
Fracture	Injury, poisoning and procedural complications	95	0.01 %
Gaze palsy	Eye disorders	95	0.01 %
Haemorrhage intracranial	Nervous system disorders	95	0.01 %
Joint dislocation	Injury, poisoning and procedural complications	95	0.01 %
Labour pain	Pregnancy, puerperium and perinatal conditions	95	0.01 %
Lung opacity	Respiratory, thoracic and mediastinal disorders	95	0.01 %
Lymphocyte count increased	Investigations	95	0.01 %
Nail discolouration	Skin and subcutaneous tissue disorders	95	0.01 %
Oesophageal pain	Gastrointestinal disorders	95	0.01 %
Atrial tachycardia	Cardiac disorders	94	0.01 %
Cardiovascular insufficiency	Cardiac disorders	94	0.01 %
Cholecystitis	Hepatobiliary disorders	94	0.01 %
Intracranial aneurysm	Nervous system disorders	94	0.01 %
Nasal herpes	Infections and infestations	94	0.01 %
Neoplasm progression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	94	0.01 %
Occupational exposure to product	Injury, poisoning and procedural complications	94	0.01 %
Respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	94	0.01 %
Spondylitis	Musculoskeletal and connective tissue disorders	94	0.01 %
Blood albumin decreased	Investigations	93	0.01 %
Diabetic ketoacidosis	Metabolism and nutrition disorders	93	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Dysgraphia	Nervous system disorders	93	0.01 %
Foetal exposure during pregnancy	Injury, poisoning and procedural complications	93	0.01 %
Hyperkalaemia	Metabolism and nutrition disorders	93	0.01 %
Lacunar infarction	Nervous system disorders	93	0.01 %
Paranoia	Psychiatric disorders	93	0.01 %
Viral rash	Infections and infestations	93	0.01 %
Affective disorder	Psychiatric disorders	92	0.01 %
Amaurosis fugax	Eye disorders	92	0.01 %
Cerebral haematoma	Nervous system disorders	92	0.01 %
Communication disorder	Psychiatric disorders	92	0.01 %
Deafness bilateral	Ear and labyrinth disorders	92	0.01 %
Depersonalisation/derealisation disorder	Psychiatric disorders	92	0.01 %
Eyelid function disorder	Eye disorders	92	0.01 %
Hypovolaemic shock	Vascular disorders	92	0.01 %
Lipase increased	Investigations	92	0.01 %
Otitis media	Infections and infestations	92	0.01 %
Thrombocytosis	Blood and lymphatic system disorders	92	0.01 %
Jaw disorder	Musculoskeletal and connective tissue disorders	91	0.01 %
Quadripareisis	Nervous system disorders	91	0.01 %
Uterine leiomyoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	91	0.01 %
Anuria	Renal and urinary disorders	90	0.01 %
SARS-CoV-2 test negative	Investigations	90	0.01 %
Testicular swelling	Reproductive system and breast disorders	90	0.01 %
Tonsillar inflammation	Respiratory, thoracic and mediastinal disorders	90	0.01 %
Cardiac failure chronic	Cardiac disorders	89	0.01 %
Increased viscosity of upper respiratory secretion	Respiratory, thoracic and mediastinal disorders	89	0.01 %
Lip erythema	Gastrointestinal disorders	89	0.01 %
Oxygen saturation abnormal	Investigations	89	0.01 %
Screaming	General disorders and administration site conditions	89	0.01 %
Thalamic infarction	Nervous system disorders	89	0.01 %
Tooth infection	Infections and infestations	89	0.01 %
Diffuse alopecia	Skin and subcutaneous tissue disorders	88	0.01 %
Osteitis	Musculoskeletal and connective tissue disorders	88	0.01 %
Slow response to stimuli	Nervous system disorders	88	0.01 %
Gastrointestinal motility disorder	Gastrointestinal disorders	87	0.01 %
Haemorrhage urinary tract	Renal and urinary disorders	87	0.01 %
Metamorphopsia	Eye disorders	87	0.01 %
Mucosal dryness	General disorders and administration site conditions	87	0.01 %
Psychogenic seizure	Nervous system disorders	87	0.01 %
Staphylococcal infection	Infections and infestations	87	0.01 %
Arteriosclerosis coronary artery	Cardiac disorders	86	0.01 %
Discharge	General disorders and administration site conditions	86	0.01 %
IIIrd nerve paralysis	Nervous system disorders	86	0.01 %
Oedema mucosal	General disorders and administration site conditions	86	0.01 %
Electrocardiogram T wave inversion	Investigations	85	0.01 %
International normalised ratio decreased	Investigations	85	0.01 %
Left ventricular failure	Cardiac disorders	85	0.01 %
Retinal vascular thrombosis	Eye disorders	85	0.01 %
Central nervous system lesion	Nervous system disorders	84	0.01 %
Daydreaming	Psychiatric disorders	84	0.01 %
General physical condition abnormal	Investigations	84	0.01 %
Haemorrhagic diathesis	Blood and lymphatic system disorders	84	0.01 %
Intracardiac thrombus	Cardiac disorders	84	0.01 %
Meningism	Nervous system disorders	84	0.01 %
Ophthalmoplegia	Eye disorders	84	0.01 %
Peritonitis	Infections and infestations	84	0.01 %
Prurigo	Skin and subcutaneous tissue disorders	84	0.01 %
Salivary gland enlargement	Gastrointestinal disorders	84	0.01 %
Salivary gland pain	Gastrointestinal disorders	84	0.01 %
Sputum discoloured	Respiratory, thoracic and mediastinal disorders	84	0.01 %
Subcutaneous haematoma	Injury, poisoning and procedural complications	84	0.01 %
Troponin abnormal	Investigations	84	0.01 %
Blood triglycerides increased	Investigations	83	0.01 %
Irregular breathing	Respiratory, thoracic and mediastinal disorders	83	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Lipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	83	0.01 %
Pulpitis dental	Infections and infestations	83	0.01 %
Pulse absent	Investigations	83	0.01 %
Retinal tear	Eye disorders	83	0.01 %
Cardiac infection	Infections and infestations	82	0.01 %
Ear haemorrhage	Ear and labyrinth disorders	82	0.01 %
Haemophagocytic lymphohistiocytosis	Immune system disorders	82	0.01 %
Injection site paraesthesia	General disorders and administration site conditions	82	0.01 %
Neutrophilia	Blood and lymphatic system disorders	82	0.01 %
Orthostatic intolerance	Nervous system disorders	82	0.01 %
Personality change	Psychiatric disorders	82	0.01 %
Polycystic ovaries	Reproductive system and breast disorders	82	0.01 %
Skin papilloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	82	0.01 %
Tonic clonic movements	Nervous system disorders	82	0.01 %
Vitreous haemorrhage	Eye disorders	82	0.01 %
Aortic valve incompetence	Cardiac disorders	81	0.01 %
Bloody discharge	Vascular disorders	81	0.01 %
Bone disorder	Musculoskeletal and connective tissue disorders	81	0.01 %
Cardiac dysfunction	Cardiac disorders	81	0.01 %
Coccydynia	Musculoskeletal and connective tissue disorders	81	0.01 %
Herpes simplex reactivation	Infections and infestations	81	0.01 %
Jugular vein thrombosis	Vascular disorders	81	0.01 %
Pharyngeal disorder	Respiratory, thoracic and mediastinal disorders	81	0.01 %
Phonophobia	Psychiatric disorders	81	0.01 %
Tendon rupture	Injury, poisoning and procedural complications	81	0.01 %
Activated partial thromboplastin time prolonged	Investigations	80	0.01 %
Arrhythmia supraventricular	Cardiac disorders	80	0.01 %
Clonus	Nervous system disorders	80	0.01 %
Hemianopia	Nervous system disorders	80	0.01 %
Hemiplegic migraine	Nervous system disorders	80	0.01 %
Hypercholesterolaemia	Metabolism and nutrition disorders	80	0.01 %
Muscle rupture	Injury, poisoning and procedural complications	80	0.01 %
Mutism	Psychiatric disorders	80	0.01 %
Proctalgia	Gastrointestinal disorders	80	0.01 %
Respiratory fatigue	Respiratory, thoracic and mediastinal disorders	80	0.01 %
Thyroid pain	Endocrine disorders	80	0.01 %
Anal haemorrhage	Gastrointestinal disorders	79	0.01 %
Arterial thrombosis	Vascular disorders	79	0.01 %
Exfoliative rash	Skin and subcutaneous tissue disorders	79	0.01 %
Food craving	Metabolism and nutrition disorders	79	0.01 %
Haemolytic anaemia	Blood and lymphatic system disorders	79	0.01 %
Injection related reaction	Injury, poisoning and procedural complications	79	0.01 %
Intestinal haemorrhage	Gastrointestinal disorders	79	0.01 %
Metabolic acidosis	Metabolism and nutrition disorders	79	0.01 %
Muscle strength abnormal	Investigations	79	0.01 %
Narcolepsy	Nervous system disorders	79	0.01 %
Product complaint	Product issues	79	0.01 %
Skin erosion	Skin and subcutaneous tissue disorders	79	0.01 %
Subcutaneous abscess	Infections and infestations	79	0.01 %
Thrombosis with thrombocytopenia syndrome	Blood and lymphatic system disorders	79	0.01 %
Tubulointerstitial nephritis	Renal and urinary disorders	79	0.01 %
Urosepsis	Infections and infestations	79	0.01 %
Vaccination site papule	General disorders and administration site conditions	79	0.01 %
IgA nephropathy	Renal and urinary disorders	78	0.01 %
Inner ear disorder	Ear and labyrinth disorders	78	0.01 %
Labile blood pressure	Vascular disorders	78	0.01 %
Laboratory test abnormal	Investigations	78	0.01 %
Oesophagitis	Gastrointestinal disorders	78	0.01 %
Product contamination physical	Product issues	78	0.01 %
Respiratory tract oedema	Respiratory, thoracic and mediastinal disorders	78	0.01 %
Sleep disorder due to a general medical condition	Psychiatric disorders	78	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Spinal disorder	Musculoskeletal and connective tissue disorders	78	0.01 %
Tachycardia paroxysmal	Cardiac disorders	78	0.01 %
Therapy partial responder	General disorders and administration site conditions	78	0.01 %
Hiatus hernia	Gastrointestinal disorders	77	0.01 %
Keratitis	Eye disorders	77	0.01 %
Lichen sclerosus	Skin and subcutaneous tissue disorders	77	0.01 %
Organising pneumonia	Respiratory, thoracic and mediastinal disorders	77	0.01 %
Pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	77	0.01 %
Vitamin D decreased	Investigations	77	0.01 %
Breath odour	Gastrointestinal disorders	76	0.01 %
Cardiac death	General disorders and administration site conditions	76	0.01 %
Foetal hypokinesia	Pregnancy, puerperium and perinatal conditions	76	0.01 %
Mast cell activation syndrome	Blood and lymphatic system disorders	76	0.01 %
Tooth abscess	Infections and infestations	76	0.01 %
Blood potassium increased	Investigations	75	0.01 %
Cardiopulmonary failure	Cardiac disorders	75	0.01 %
III-defined disorder	General disorders and administration site conditions	75	0.01 %
Mucosal disorder	General disorders and administration site conditions	75	0.01 %
Poor feeding infant	Metabolism and nutrition disorders	75	0.01 %
Scar pain	Skin and subcutaneous tissue disorders	75	0.01 %
Skin depigmentation	Skin and subcutaneous tissue disorders	75	0.01 %
Still's disease	Musculoskeletal and connective tissue disorders	75	0.01 %
Throat clearing	Respiratory, thoracic and mediastinal disorders	75	0.01 %
Blood immunoglobulin E increased	Investigations	74	0.01 %
Guttate psoriasis	Skin and subcutaneous tissue disorders	74	0.01 %
Infantile vomiting	Gastrointestinal disorders	74	0.01 %
Micturition disorder	Renal and urinary disorders	74	0.01 %
Plantar fasciitis	Musculoskeletal and connective tissue disorders	74	0.01 %
Pupils unequal	Eye disorders	74	0.01 %
Skin induration	Skin and subcutaneous tissue disorders	74	0.01 %
Sleep paralysis	Nervous system disorders	74	0.01 %
Splenic infarction	Blood and lymphatic system disorders	74	0.01 %
Stevens-Johnson syndrome	Skin and subcutaneous tissue disorders	74	0.01 %
Behaviour disorder	Psychiatric disorders	73	0.01 %
Dermatomyositis	Skin and subcutaneous tissue disorders	73	0.01 %
Epididymitis	Infections and infestations	73	0.01 %
Haemorrhage in pregnancy	Pregnancy, puerperium and perinatal conditions	73	0.01 %
Injection site urticaria	General disorders and administration site conditions	73	0.01 %
Laryngeal pain	Respiratory, thoracic and mediastinal disorders	73	0.01 %
Renal cyst	Renal and urinary disorders	73	0.01 %
Acute vestibular syndrome	Ear and labyrinth disorders	72	0.01 %
Blood lactic acid increased	Investigations	72	0.01 %
Cerebral artery embolism	Nervous system disorders	72	0.01 %
Injection site muscle weakness	General disorders and administration site conditions	72	0.01 %
Oliguria	Renal and urinary disorders	72	0.01 %
Oral dysaesthesia	Gastrointestinal disorders	72	0.01 %
Pleuropericarditis	Cardiac disorders	72	0.01 %
Protein urine present	Investigations	72	0.01 %
Appendicitis perforated	Infections and infestations	71	0.01 %
Breast discharge	Reproductive system and breast disorders	71	0.01 %
Enuresis	Psychiatric disorders	71	0.01 %
Eyelid rash	Eye disorders	71	0.01 %
Hand dermatitis	Skin and subcutaneous tissue disorders	71	0.01 %
Hypoventilation	Respiratory, thoracic and mediastinal disorders	71	0.01 %
Malnutrition	Metabolism and nutrition disorders	71	0.01 %
Myopathy	Musculoskeletal and connective tissue disorders	71	0.01 %
Otitis externa	Infections and infestations	71	0.01 %
Snoring	Respiratory, thoracic and mediastinal disorders	71	0.01 %
Vulvovaginal pruritus	Reproductive system and breast disorders	71	0.01 %
Allergic reaction to excipient	Immune system disorders	70	0.01 %
Blood urine	Investigations	70	0.01 %
Crepitations	General disorders and administration site conditions	70	0.01 %
Glomerulonephritis	Renal and urinary disorders	70	0.01 %
Pharyngitis streptococcal	Infections and infestations	70	0.01 %
Skin weeping	Skin and subcutaneous tissue disorders	70	0.01 %
Use of accessory respiratory muscles	Respiratory, thoracic and mediastinal disorders	70	0.01 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vaccination site extravasation	General disorders and administration site conditions	70	0.01 %
Vascular purpura	Skin and subcutaneous tissue disorders	70	0.01 %
Vasculitic rash	Skin and subcutaneous tissue disorders	70	0.01 %
Dystonia	Nervous system disorders	69	0.01 %
Electrocardiogram ST segment depression	Investigations	69	0.01 %
Eye allergy	Eye disorders	69	0.01 %
Larynx irritation	Respiratory, thoracic and mediastinal disorders	69	0.01 %
Mucosal inflammation	General disorders and administration site conditions	69	0.01 %
Vaccination site coldness	General disorders and administration site conditions	69	0.01 %
Antiphospholipid syndrome	Blood and lymphatic system disorders	68	0.01 %
Aptyalism	Gastrointestinal disorders	68	0.01 %
Breast disorder	Reproductive system and breast disorders	68	0.01 %
Fluid intake reduced	Metabolism and nutrition disorders	68	0.01 %
Haemolysis	Blood and lymphatic system disorders	68	0.01 %
Head titubation	Nervous system disorders	68	0.01 %
Hidradenitis	Skin and subcutaneous tissue disorders	68	0.01 %
Impetigo	Infections and infestations	68	0.01 %
Miller Fisher syndrome	Nervous system disorders	68	0.01 %
Nocturia	Renal and urinary disorders	68	0.01 %
Upper limb fracture	Injury, poisoning and procedural complications	68	0.01 %
Uterine contractions during pregnancy	Pregnancy, puerperium and perinatal conditions	68	0.01 %
Acute polyneuropathy	Nervous system disorders	67	0.00 %
Angina unstable	Cardiac disorders	67	0.00 %
Blood uric acid increased	Investigations	67	0.00 %
Blue toe syndrome	Vascular disorders	67	0.00 %
Bruxism	Psychiatric disorders	67	0.00 %
Circumoral swelling	Skin and subcutaneous tissue disorders	67	0.00 %
Ectopic pregnancy	Pregnancy, puerperium and perinatal conditions	67	0.00 %
Injection site discomfort	General disorders and administration site conditions	67	0.00 %
Multisystem inflammatory syndrome in children	Immune system disorders	67	0.00 %
Right ventricular failure	Cardiac disorders	67	0.00 %
Terminal insomnia	Psychiatric disorders	67	0.00 %
Tongue eruption	Gastrointestinal disorders	67	0.00 %
Cutaneous symptom	Skin and subcutaneous tissue disorders	66	0.00 %
Dyschezia	Gastrointestinal disorders	66	0.00 %
Galactorrhoea	Reproductive system and breast disorders	66	0.00 %
Hypoalbuminaemia	Metabolism and nutrition disorders	66	0.00 %
Oral fungal infection	Infections and infestations	66	0.00 %
Physical disability	Social circumstances	66	0.00 %
Red blood cell count increased	Investigations	66	0.00 %
Serum ferritin decreased	Investigations	66	0.00 %
Sputum increased	Respiratory, thoracic and mediastinal disorders	66	0.00 %
Acquired haemophilia	Blood and lymphatic system disorders	65	0.00 %
Facial bones fracture	Injury, poisoning and procedural complications	65	0.00 %
Fear of injection	Psychiatric disorders	65	0.00 %
Haemoglobin increased	Investigations	65	0.00 %
Peripheral arterial occlusive disease	Vascular disorders	65	0.00 %
Peripheral embolism	Vascular disorders	65	0.00 %
Reduced facial expression	Nervous system disorders	65	0.00 %
Sensorimotor disorder	Nervous system disorders	65	0.00 %
Symptom recurrence	General disorders and administration site conditions	65	0.00 %
Urine analysis abnormal	Investigations	65	0.00 %
Gastric ulcer	Gastrointestinal disorders	64	0.00 %
Histamine intolerance	Metabolism and nutrition disorders	64	0.00 %
Idiopathic intracranial hypertension	Nervous system disorders	64	0.00 %
Inflammatory bowel disease	Gastrointestinal disorders	64	0.00 %
Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	64	0.00 %
Pemphigus	Skin and subcutaneous tissue disorders	64	0.00 %
Premature labour	Pregnancy, puerperium and perinatal conditions	64	0.00 %
Renal infarct	Renal and urinary disorders	64	0.00 %
Tracheitis	Infections and infestations	64	0.00 %
Vaccine breakthrough infection	Infections and infestations	64	0.00 %
Wound haemorrhage	Injury, poisoning and procedural complications	64	0.00 %
Bed rest	Surgical and medical procedures	63	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Chorioretinopathy	Eye disorders	63	0.00 %
Echocardiogram abnormal	Investigations	63	0.00 %
Episcleritis	Eye disorders	63	0.00 %
Paraplegia	Nervous system disorders	63	0.00 %
Prostatic specific antigen increased	Investigations	63	0.00 %
Pruritus genital	Reproductive system and breast disorders	63	0.00 %
Psychiatric symptom	Psychiatric disorders	63	0.00 %
Reading disorder	Psychiatric disorders	63	0.00 %
Thyroid function test abnormal	Investigations	63	0.00 %
Tongue paralysis	Nervous system disorders	63	0.00 %
Ventricular arrhythmia	Cardiac disorders	63	0.00 %
Vestibular migraine	Nervous system disorders	63	0.00 %
Vulvovaginal burning sensation	Reproductive system and breast disorders	63	0.00 %
Apraxia	Nervous system disorders	62	0.00 %
Atrioventricular block second degree	Cardiac disorders	62	0.00 %
Gynaecomastia	Reproductive system and breast disorders	62	0.00 %
Irritability postvaccinal	General disorders and administration site conditions	62	0.00 %
Madarosis	Skin and subcutaneous tissue disorders	62	0.00 %
Morning sickness	Pregnancy, puerperium and perinatal conditions	62	0.00 %
Product colour issue	Product issues	62	0.00 %
Band sensation	Nervous system disorders	61	0.00 %
Bladder discomfort	Renal and urinary disorders	61	0.00 %
Cardiac hypertrophy	Cardiac disorders	61	0.00 %
Craniocerebral injury	Injury, poisoning and procedural complications	61	0.00 %
Embolism venous	Vascular disorders	61	0.00 %
Eye haematoma	Eye disorders	61	0.00 %
Vaginal infection	Infections and infestations	61	0.00 %
Cerebellar haemorrhage	Nervous system disorders	60	0.00 %
Cerebellar stroke	Nervous system disorders	60	0.00 %
Deafness transitory	Ear and labyrinth disorders	60	0.00 %
Demyelinating polyneuropathy	Nervous system disorders	60	0.00 %
Folate deficiency	Metabolism and nutrition disorders	60	0.00 %
Granuloma annulare	Skin and subcutaneous tissue disorders	60	0.00 %
Haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	60	0.00 %
Haematocrit increased	Investigations	60	0.00 %
Hydrocephalus	Nervous system disorders	60	0.00 %
Hypercoagulation	Blood and lymphatic system disorders	60	0.00 %
Infertility	Reproductive system and breast disorders	60	0.00 %
Lymphocytosis	Blood and lymphatic system disorders	60	0.00 %
Myokymia	Musculoskeletal and connective tissue disorders	60	0.00 %
Ocular hypertension	Eye disorders	60	0.00 %
Radiculitis brachial	Nervous system disorders	60	0.00 %
Sensation of blood flow	General disorders and administration site conditions	60	0.00 %
Tongue movement disturbance	Gastrointestinal disorders	60	0.00 %
Vulvovaginal discomfort	Reproductive system and breast disorders	60	0.00 %
Acne cystic	Skin and subcutaneous tissue disorders	59	0.00 %
Amylase increased	Investigations	59	0.00 %
Gallbladder disorder	Hepatobiliary disorders	59	0.00 %
Gingival discomfort	Gastrointestinal disorders	59	0.00 %
Hyperreflexia	Nervous system disorders	59	0.00 %
Intermittent claudication	Vascular disorders	59	0.00 %
Quadriplegia	Nervous system disorders	59	0.00 %
Abortion	Pregnancy, puerperium and perinatal conditions	58	0.00 %
Accommodation disorder	Eye disorders	58	0.00 %
Body height decreased	Investigations	58	0.00 %
Cold urticaria	Skin and subcutaneous tissue disorders	58	0.00 %
Cold-stimulus headache	Nervous system disorders	58	0.00 %
Coronavirus infection	Infections and infestations	58	0.00 %
Encephalitis autoimmune	Nervous system disorders	58	0.00 %
Foaming at mouth	General disorders and administration site conditions	58	0.00 %
Hepatic enzyme abnormal	Investigations	58	0.00 %
Intercostal neuralgia	Nervous system disorders	58	0.00 %
Joint ankylosis	Musculoskeletal and connective tissue disorders	58	0.00 %
Limb immobilisation	Surgical and medical procedures	58	0.00 %
Mental status changes	Psychiatric disorders	58	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Myocardial fibrosis	Cardiac disorders	58	0.00 %
Neuromyelitis optica spectrum disorder	Nervous system disorders	58	0.00 %
Ocular icterus	Hepatobiliary disorders	58	0.00 %
Premature menopause	Reproductive system and breast disorders	58	0.00 %
Pulmonary function test decreased	Investigations	58	0.00 %
Sensitisation	Immune system disorders	58	0.00 %
Skin hyperpigmentation	Skin and subcutaneous tissue disorders	58	0.00 %
Skin oedema	Skin and subcutaneous tissue disorders	58	0.00 %
Sleep terror	Psychiatric disorders	58	0.00 %
Tooth fracture	Injury, poisoning and procedural complications	58	0.00 %
Allergy to arthropod sting	Immune system disorders	57	0.00 %
Capillary leak syndrome	Vascular disorders	57	0.00 %
Cerebral artery occlusion	Nervous system disorders	57	0.00 %
Cerebral artery thrombosis	Nervous system disorders	57	0.00 %
Conjunctivitis allergic	Eye disorders	57	0.00 %
Dementia Alzheimer's type	Nervous system disorders	57	0.00 %
Dental discomfort	Gastrointestinal disorders	57	0.00 %
Effusion	General disorders and administration site conditions	57	0.00 %
Food poisoning	Gastrointestinal disorders	57	0.00 %
Increased bronchial secretion	Respiratory, thoracic and mediastinal disorders	57	0.00 %
Lip discolouration	Gastrointestinal disorders	57	0.00 %
Lung neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	57	0.00 %
Meningitis viral	Infections and infestations	57	0.00 %
Moaning	General disorders and administration site conditions	57	0.00 %
Reflux gastritis	Gastrointestinal disorders	57	0.00 %
Rhonchi	Respiratory, thoracic and mediastinal disorders	57	0.00 %
Scintillating scotoma	Eye disorders	57	0.00 %
Sopor	Psychiatric disorders	57	0.00 %
Telangiectasia	Skin and subcutaneous tissue disorders	57	0.00 %
Vocal cord paralysis	Nervous system disorders	57	0.00 %
Vulval ulceration	Reproductive system and breast disorders	57	0.00 %
Accident	Injury, poisoning and procedural complications	56	0.00 %
Carotid artery dissection	Nervous system disorders	56	0.00 %
Coma scale abnormal	Investigations	56	0.00 %
Dermatitis exfoliative generalised	Skin and subcutaneous tissue disorders	56	0.00 %
Retinal migraine	Nervous system disorders	56	0.00 %
Skin hypertrophy	Skin and subcutaneous tissue disorders	56	0.00 %
Skin injury	Injury, poisoning and procedural complications	56	0.00 %
Stillbirth	Pregnancy, puerperium and perinatal conditions	56	0.00 %
White matter lesion	Nervous system disorders	56	0.00 %
Aortic arteriosclerosis	Vascular disorders	55	0.00 %
Arthropod sting	Injury, poisoning and procedural complications	55	0.00 %
Cachexia	Metabolism and nutrition disorders	55	0.00 %
Disorganised speech	Psychiatric disorders	55	0.00 %
Hair growth abnormal	Skin and subcutaneous tissue disorders	55	0.00 %
Heat stroke	Injury, poisoning and procedural complications	55	0.00 %
Hypernatraemia	Metabolism and nutrition disorders	55	0.00 %
Intervertebral disc disorder	Musculoskeletal and connective tissue disorders	55	0.00 %
Lip ulceration	Gastrointestinal disorders	55	0.00 %
Noninfective encephalitis	Nervous system disorders	55	0.00 %
Osteoporosis	Musculoskeletal and connective tissue disorders	55	0.00 %
Thunderclap headache	Nervous system disorders	55	0.00 %
Bronchial disorder	Respiratory, thoracic and mediastinal disorders	54	0.00 %
C-reactive protein abnormal	Investigations	54	0.00 %
Change of bowel habit	Gastrointestinal disorders	54	0.00 %
Dermal cyst	Skin and subcutaneous tissue disorders	54	0.00 %
Dermatitis psoriasiform	Skin and subcutaneous tissue disorders	54	0.00 %
Electrolyte imbalance	Metabolism and nutrition disorders	54	0.00 %
Eye paraesthesia	Eye disorders	54	0.00 %
Hair texture abnormal	Skin and subcutaneous tissue disorders	54	0.00 %
Injection site bruising	General disorders and administration site conditions	54	0.00 %
Macular degeneration	Eye disorders	54	0.00 %
Myocardial oedema	Cardiac disorders	54	0.00 %
Otorrhoea	Ear and labyrinth disorders	54	0.00 %
Vaccination site dysaesthesia	General disorders and administration site conditions	54	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vaccination site eczema	General disorders and administration site conditions	54	0.00 %
Vulvovaginal dryness	Reproductive system and breast disorders	54	0.00 %
Walking aid user	Social circumstances	54	0.00 %
Withdrawal syndrome	General disorders and administration site conditions	54	0.00 %
Allergy to arthropod bite	Immune system disorders	53	0.00 %
Aortic aneurysm	Vascular disorders	53	0.00 %
Carotid artery stenosis	Nervous system disorders	53	0.00 %
Decubitus ulcer	Skin and subcutaneous tissue disorders	53	0.00 %
Galactostasis	Reproductive system and breast disorders	53	0.00 %
Laziness	Psychiatric disorders	53	0.00 %
Lip injury	Injury, poisoning and procedural complications	53	0.00 %
Major depression	Psychiatric disorders	53	0.00 %
Mania	Psychiatric disorders	53	0.00 %
Necrosis	General disorders and administration site conditions	53	0.00 %
Protein total decreased	Investigations	53	0.00 %
Rheumatoid factor increased	Investigations	53	0.00 %
Troponin	Investigations	53	0.00 %
Vaccination site scar	General disorders and administration site conditions	53	0.00 %
Wound complication	Injury, poisoning and procedural complications	53	0.00 %
Adrenocortical insufficiency acute	Endocrine disorders	52	0.00 %
Allergic oedema	Immune system disorders	52	0.00 %
Back injury	Injury, poisoning and procedural complications	52	0.00 %
Blood pressure measurement	Investigations	52	0.00 %
Cerebral atrophy	Nervous system disorders	52	0.00 %
Chalazion	Eye disorders	52	0.00 %
Chronic inflammatory demyelinating polyradiculoneuropathy	Nervous system disorders	52	0.00 %
Colitis microscopic	Gastrointestinal disorders	52	0.00 %
Disability	Social circumstances	52	0.00 %
Dyslipidaemia	Metabolism and nutrition disorders	52	0.00 %
Glomerulonephritis minimal lesion	Renal and urinary disorders	52	0.00 %
Hepatic cyst	Hepatobiliary disorders	52	0.00 %
Hypertensive emergency	Vascular disorders	52	0.00 %
Impaired gastric emptying	Gastrointestinal disorders	52	0.00 %
Leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	52	0.00 %
Miosis	Eye disorders	52	0.00 %
Orchitis	Infections and infestations	52	0.00 %
Oropharyngeal blistering	Respiratory, thoracic and mediastinal disorders	52	0.00 %
Posture abnormal	Musculoskeletal and connective tissue disorders	52	0.00 %
Spider vein	Vascular disorders	52	0.00 %
Therapeutic product effect decreased	General disorders and administration site conditions	52	0.00 %
Thyroiditis acute	Endocrine disorders	52	0.00 %
Upper gastrointestinal haemorrhage	Gastrointestinal disorders	52	0.00 %
Atypical pneumonia	Infections and infestations	51	0.00 %
Burning sensation mucosal	Nervous system disorders	51	0.00 %
Carotid artery occlusion	Nervous system disorders	51	0.00 %
Coeliac disease	Gastrointestinal disorders	51	0.00 %
Cytomegalovirus infection	Infections and infestations	51	0.00 %
Drug-induced liver injury	Hepatobiliary disorders	51	0.00 %
Ear inflammation	Ear and labyrinth disorders	51	0.00 %
Hallucination, olfactory	Psychiatric disorders	51	0.00 %
Inappropriate affect	Psychiatric disorders	51	0.00 %
Infant irritability	Nervous system disorders	51	0.00 %
Injection site haematoma	General disorders and administration site conditions	51	0.00 %
Lymphadenopathy mediastinal	Blood and lymphatic system disorders	51	0.00 %
Myopia	Eye disorders	51	0.00 %
Pruritus allergic	Skin and subcutaneous tissue disorders	51	0.00 %
Skin wrinkling	Skin and subcutaneous tissue disorders	51	0.00 %
Suicide attempt	Psychiatric disorders	51	0.00 %
Urinary tract infection bacterial	Infections and infestations	51	0.00 %
Abscess limb	Infections and infestations	50	0.00 %
Cardiac valve disease	Cardiac disorders	50	0.00 %
Carotid arteriosclerosis	Nervous system disorders	50	0.00 %
Dark circles under eyes	Eye disorders	50	0.00 %
Dyschromatopsia	Eye disorders	50	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Eczema nummular	Skin and subcutaneous tissue disorders	50	0.00 %
Endocrine disorder	Endocrine disorders	50	0.00 %
Foot deformity	Musculoskeletal and connective tissue disorders	50	0.00 %
Hemianopia homonymous	Nervous system disorders	50	0.00 %
Hip fracture	Injury, poisoning and procedural complications	50	0.00 %
Hyperchlorydria	Gastrointestinal disorders	50	0.00 %
Hypersensitivity vasculitis	Skin and subcutaneous tissue disorders	50	0.00 %
Hyporesponsive to stimuli	Nervous system disorders	50	0.00 %
Myelodysplastic syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	50	0.00 %
Nasal disorder	Respiratory, thoracic and mediastinal disorders	50	0.00 %
No adverse event	General disorders and administration site conditions	50	0.00 %
Oral blood blister	Gastrointestinal disorders	50	0.00 %
Periorbital pain	Eye disorders	50	0.00 %
Prothrombin time prolonged	Investigations	50	0.00 %
Seizure like phenomena	Nervous system disorders	50	0.00 %
Vertebral artery dissection	Nervous system disorders	50	0.00 %
Behcet's syndrome	Vascular disorders	49	0.00 %
Decreased interest	Psychiatric disorders	49	0.00 %
Electrocardiogram repolarisation abnormality	Investigations	49	0.00 %
Faeces pale	Gastrointestinal disorders	49	0.00 %
Hypogammaglobulinaemia	Immune system disorders	49	0.00 %
Leukoencephalopathy	Nervous system disorders	49	0.00 %
Normocytic anaemia	Blood and lymphatic system disorders	49	0.00 %
Oropharyngeal swelling	Respiratory, thoracic and mediastinal disorders	49	0.00 %
Oversensing	Product issues	49	0.00 %
Scleritis	Eye disorders	49	0.00 %
Urticarial vasculitis	Skin and subcutaneous tissue disorders	49	0.00 %
Vascular injury	Injury, poisoning and procedural complications	49	0.00 %
Blood calcium decreased	Investigations	48	0.00 %
Blood creatinine decreased	Investigations	48	0.00 %
Bronchial hyperreactivity	Respiratory, thoracic and mediastinal disorders	48	0.00 %
Chronic spontaneous urticaria	Skin and subcutaneous tissue disorders	48	0.00 %
Diverticulum intestinal	Gastrointestinal disorders	48	0.00 %
Enterocolitis	Gastrointestinal disorders	48	0.00 %
Enthesopathy	Musculoskeletal and connective tissue disorders	48	0.00 %
Finger deformity	Musculoskeletal and connective tissue disorders	48	0.00 %
Fungal skin infection	Infections and infestations	48	0.00 %
Haemodynamic instability	Vascular disorders	48	0.00 %
Head banging	Psychiatric disorders	48	0.00 %
Lymphatic disorder	Blood and lymphatic system disorders	48	0.00 %
Ruptured cerebral aneurysm	Nervous system disorders	48	0.00 %
Sialoadenitis	Infections and infestations	48	0.00 %
Sinus rhythm	Investigations	48	0.00 %
Tonsillar disorder	Respiratory, thoracic and mediastinal disorders	48	0.00 %
Vaccination site pustule	Infections and infestations	48	0.00 %
Vaccination site scab	General disorders and administration site conditions	48	0.00 %
Autoscopy	Psychiatric disorders	47	0.00 %
Blood creatine increased	Investigations	47	0.00 %
Brain death	General disorders and administration site conditions	47	0.00 %
Cranial nerve disorder	Nervous system disorders	47	0.00 %
Drug intolerance	General disorders and administration site conditions	47	0.00 %
Eczema eyelids	Eye disorders	47	0.00 %
Escherichia urinary tract infection	Infections and infestations	47	0.00 %
Eyelid haematoma	Eye disorders	47	0.00 %
Platelet disorder	Blood and lymphatic system disorders	47	0.00 %
Pulmonary alveolar haemorrhage	Respiratory, thoracic and mediastinal disorders	47	0.00 %
Regurgitation	Gastrointestinal disorders	47	0.00 %
Streptococcal infection	Infections and infestations	47	0.00 %
Sudden onset of sleep	Nervous system disorders	47	0.00 %
Vein discolouration	Vascular disorders	47	0.00 %
Vitamin B12 deficiency	Metabolism and nutrition disorders	47	0.00 %
Bleeding time prolonged	Investigations	46	0.00 %
Coital bleeding	Reproductive system and breast disorders	46	0.00 %
Congenital anomaly	Congenital, familial and genetic disorders	46	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Electrocardiogram	Investigations	46	0.00 %
Exophthalmos	Eye disorders	46	0.00 %
Femur fracture	Injury, poisoning and procedural complications	46	0.00 %
Heat illness	Injury, poisoning and procedural complications	46	0.00 %
Hypertensive heart disease	Cardiac disorders	46	0.00 %
Hypertransaminasaemia	Hepatobiliary disorders	46	0.00 %
Hypoxic-ischaemic encephalopathy	Nervous system disorders	46	0.00 %
Ileus	Gastrointestinal disorders	46	0.00 %
Injection site haemorrhage	General disorders and administration site conditions	46	0.00 %
Lividity	Skin and subcutaneous tissue disorders	46	0.00 %
Myopathy	Nervous system disorders	46	0.00 %
Nocturnal dyspnoea	Respiratory, thoracic and mediastinal disorders	46	0.00 %
Noninfective sialoadenitis	Gastrointestinal disorders	46	0.00 %
Oral lichen planus	Gastrointestinal disorders	46	0.00 %
Organ failure	General disorders and administration site conditions	46	0.00 %
Tendon discomfort	Musculoskeletal and connective tissue disorders	46	0.00 %
Varicophlebitis	Vascular disorders	46	0.00 %
Vascular rupture	Vascular disorders	46	0.00 %
Vitamin B12 decreased	Investigations	46	0.00 %
Adrenal insufficiency	Endocrine disorders	45	0.00 %
Amnestic disorder	Nervous system disorders	45	0.00 %
Atrioventricular block first degree	Cardiac disorders	45	0.00 %
Brain neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	45	0.00 %
Eye infarction	Eye disorders	45	0.00 %
Genital rash	Reproductive system and breast disorders	45	0.00 %
Genital ulceration	Reproductive system and breast disorders	45	0.00 %
Haematoma muscle	Musculoskeletal and connective tissue disorders	45	0.00 %
Hernia	General disorders and administration site conditions	45	0.00 %
Herpes zoster meningitis	Infections and infestations	45	0.00 %
Hyperbilirubinaemia	Hepatobiliary disorders	45	0.00 %
Lactation puerperal increased	Reproductive system and breast disorders	45	0.00 %
Melanocytic naevus	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	45	0.00 %
Multiple allergies	Immune system disorders	45	0.00 %
New daily persistent headache	Nervous system disorders	45	0.00 %
Nipple swelling	Reproductive system and breast disorders	45	0.00 %
Pharyngeal ulceration	Respiratory, thoracic and mediastinal disorders	45	0.00 %
Post-traumatic stress disorder	Psychiatric disorders	45	0.00 %
Premenstrual dysphoric disorder	Reproductive system and breast disorders	45	0.00 %
Respiratory acidosis	Respiratory, thoracic and mediastinal disorders	45	0.00 %
Respiratory alkalosis	Respiratory, thoracic and mediastinal disorders	45	0.00 %
Thalamus haemorrhage	Nervous system disorders	45	0.00 %
Vaccination site joint inflammation	General disorders and administration site conditions	45	0.00 %
Venous occlusion	Vascular disorders	45	0.00 %
Viral pericarditis	Infections and infestations	45	0.00 %
White blood cell disorder	Blood and lymphatic system disorders	45	0.00 %
Acute myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	44	0.00 %
Aplastic anaemia	Blood and lymphatic system disorders	44	0.00 %
Bacteraemia	Infections and infestations	44	0.00 %
Brain stem haemorrhage	Nervous system disorders	44	0.00 %
Bronchiectasis	Respiratory, thoracic and mediastinal disorders	44	0.00 %
Electrocardiogram QT prolonged	Investigations	44	0.00 %
Food refusal	Metabolism and nutrition disorders	44	0.00 %
Haemorrhagic disorder	Blood and lymphatic system disorders	44	0.00 %
Heart sounds abnormal	Investigations	44	0.00 %
Nasal inflammation	Respiratory, thoracic and mediastinal disorders	44	0.00 %
Ovarian cyst ruptured	Reproductive system and breast disorders	44	0.00 %
Parkinsonism	Nervous system disorders	44	0.00 %
Pharyngeal mass	Respiratory, thoracic and mediastinal disorders	44	0.00 %
Premature delivery	Pregnancy, puerperium and perinatal conditions	44	0.00 %
Radial nerve palsy	Nervous system disorders	44	0.00 %
Tooth injury	Injury, poisoning and procedural complications	44	0.00 %
Viral myocarditis	Infections and infestations	44	0.00 %
Bacterial test positive	Investigations	43	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Blood pressure immeasurable	Investigations	43	0.00 %
Blood pressure inadequately controlled	Vascular disorders	43	0.00 %
Chronic lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	43	0.00 %
Cough variant asthma	Respiratory, thoracic and mediastinal disorders	43	0.00 %
Distractibility	Psychiatric disorders	43	0.00 %
Foreign body in throat	Injury, poisoning and procedural complications	43	0.00 %
Gingival blister	Gastrointestinal disorders	43	0.00 %
Haemarthrosis	Musculoskeletal and connective tissue disorders	43	0.00 %
Haematospermia	Reproductive system and breast disorders	43	0.00 %
Immune-mediated adverse reaction	Immune system disorders	43	0.00 %
Lagophthalmos	Eye disorders	43	0.00 %
Lichenoid keratosis	Skin and subcutaneous tissue disorders	43	0.00 %
Meningoencephalitis herpetic	Infections and infestations	43	0.00 %
Neurogenic shock	Vascular disorders	43	0.00 %
Stenosis	General disorders and administration site conditions	43	0.00 %
Urinary tract disorder	Renal and urinary disorders	43	0.00 %
Vaccination site discharge	General disorders and administration site conditions	43	0.00 %
Acute generalised exanthematous pustulosis	Skin and subcutaneous tissue disorders	42	0.00 %
Acute sinusitis	Infections and infestations	42	0.00 %
Aneurysm ruptured	Vascular disorders	42	0.00 %
Antinuclear antibody increased	Investigations	42	0.00 %
Blood immunoglobulin G increased	Investigations	42	0.00 %
Butterfly rash	Skin and subcutaneous tissue disorders	42	0.00 %
Central nervous system inflammation	Nervous system disorders	42	0.00 %
Clonic convulsion	Nervous system disorders	42	0.00 %
Electric shock	Injury, poisoning and procedural complications	42	0.00 %
Endometrial thickening	Reproductive system and breast disorders	42	0.00 %
Flat affect	Psychiatric disorders	42	0.00 %
Gastric dilatation	Gastrointestinal disorders	42	0.00 %
Gastric haemorrhage	Gastrointestinal disorders	42	0.00 %
Genital burning sensation	Reproductive system and breast disorders	42	0.00 %
Gingival disorder	Gastrointestinal disorders	42	0.00 %
Hemidysaesthesia	Nervous system disorders	42	0.00 %
Hepatic cirrhosis	Hepatobiliary disorders	42	0.00 %
Lymph gland infection	Infections and infestations	42	0.00 %
Migraine without aura	Nervous system disorders	42	0.00 %
Multisystem inflammatory syndrome	Immune system disorders	42	0.00 %
Oculomucocutaneous syndrome	Skin and subcutaneous tissue disorders	42	0.00 %
Panniculitis	Skin and subcutaneous tissue disorders	42	0.00 %
Pericardial disease	Cardiac disorders	42	0.00 %
Pityriasis	Skin and subcutaneous tissue disorders	42	0.00 %
Polyp	General disorders and administration site conditions	42	0.00 %
Seborrhoea	Skin and subcutaneous tissue disorders	42	0.00 %
Staring	Psychiatric disorders	42	0.00 %
Urinary tract inflammation	Renal and urinary disorders	42	0.00 %
Viral pharyngitis	Infections and infestations	42	0.00 %
White blood cells urine positive	Investigations	42	0.00 %
Abnormal weight gain	Metabolism and nutrition disorders	41	0.00 %
Adenomyosis	Reproductive system and breast disorders	41	0.00 %
Akathisia	Nervous system disorders	41	0.00 %
Alcohol intolerance	Metabolism and nutrition disorders	41	0.00 %
Breast abscess	Infections and infestations	41	0.00 %
Carotid artery thrombosis	Nervous system disorders	41	0.00 %
Chest X-ray abnormal	Investigations	41	0.00 %
Excessive cerumen production	Ear and labyrinth disorders	41	0.00 %
Faecaloma	Gastrointestinal disorders	41	0.00 %
Foetal heart rate abnormal	Investigations	41	0.00 %
Lack of spontaneous speech	Psychiatric disorders	41	0.00 %
Osteomyelitis	Infections and infestations	41	0.00 %
Peripheral artery occlusion	Vascular disorders	41	0.00 %
PO2 decreased	Investigations	41	0.00 %
Psychomotor skills impaired	Nervous system disorders	41	0.00 %
Respiratory depression	Respiratory, thoracic and mediastinal disorders	41	0.00 %
Seborrhoeic dermatitis	Skin and subcutaneous tissue disorders	41	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Seronegative arthritis	Musculoskeletal and connective tissue disorders	41	0.00 %
Somnambulism	Psychiatric disorders	41	0.00 %
Spinal cord disorder	Nervous system disorders	41	0.00 %
Spinal fracture	Injury, poisoning and procedural complications	41	0.00 %
Teething	Gastrointestinal disorders	41	0.00 %
Vaccination site nerve damage	General disorders and administration site conditions	41	0.00 %
Vasoconstriction	Vascular disorders	41	0.00 %
Cell death	Metabolism and nutrition disorders	40	0.00 %
Depressive symptom	Psychiatric disorders	40	0.00 %
Diastolic dysfunction	Cardiac disorders	40	0.00 %
Freezing phenomenon	Nervous system disorders	40	0.00 %
General symptom	General disorders and administration site conditions	40	0.00 %
Glassy eyes	General disorders and administration site conditions	40	0.00 %
Haemorrhoidal haemorrhage	Gastrointestinal disorders	40	0.00 %
Heat exhaustion	Injury, poisoning and procedural complications	40	0.00 %
Hyperlipidaemia	Metabolism and nutrition disorders	40	0.00 %
Hypertrophic cardiomyopathy	Congenital, familial and genetic disorders	40	0.00 %
Hypervolaemia	Metabolism and nutrition disorders	40	0.00 %
Lactic acidosis	Metabolism and nutrition disorders	40	0.00 %
Menarche	Social circumstances	40	0.00 %
Menstruation normal	Investigations	40	0.00 %
Nail disorder	Skin and subcutaneous tissue disorders	40	0.00 %
Neurologic neglect syndrome	Nervous system disorders	40	0.00 %
Premenstrual headache	Reproductive system and breast disorders	40	0.00 %
Pulmonary haemorrhage	Respiratory, thoracic and mediastinal disorders	40	0.00 %
Scrotal pain	Reproductive system and breast disorders	40	0.00 %
Shock haemorrhagic	Vascular disorders	40	0.00 %
Spinal stenosis	Musculoskeletal and connective tissue disorders	40	0.00 %
Suspected counterfeit product	Product issues	40	0.00 %
Tooth loss	Gastrointestinal disorders	40	0.00 %
Total lung capacity decreased	Investigations	40	0.00 %
Toxicity to various agents	Injury, poisoning and procedural complications	40	0.00 %
Uterine contractions abnormal	Pregnancy, puerperium and perinatal conditions	40	0.00 %
Vascular occlusion	Vascular disorders	40	0.00 %
Acidosis	Metabolism and nutrition disorders	39	0.00 %
Amyotrophic lateral sclerosis	Nervous system disorders	39	0.00 %
Breast induration	Reproductive system and breast disorders	39	0.00 %
Burning mouth syndrome	Gastrointestinal disorders	39	0.00 %
Gingival oedema	Gastrointestinal disorders	39	0.00 %
Grunting	Respiratory, thoracic and mediastinal disorders	39	0.00 %
Hand deformity	Musculoskeletal and connective tissue disorders	39	0.00 %
Heart disease congenital	Congenital, familial and genetic disorders	39	0.00 %
Hypercapnia	Respiratory, thoracic and mediastinal disorders	39	0.00 %
Immunisation anxiety related reaction	Psychiatric disorders	39	0.00 %
Intervertebral disc degeneration	Musculoskeletal and connective tissue disorders	39	0.00 %
Libido increased	Psychiatric disorders	39	0.00 %
Mitral valve prolapse	Cardiac disorders	39	0.00 %
Nephropathy	Renal and urinary disorders	39	0.00 %
Neurosensory hypoacusis	Ear and labyrinth disorders	39	0.00 %
Pericardial haemorrhage	Cardiac disorders	39	0.00 %
Pulmonary artery thrombosis	Respiratory, thoracic and mediastinal disorders	39	0.00 %
Skin necrosis	Skin and subcutaneous tissue disorders	39	0.00 %
Superior sagittal sinus thrombosis	Nervous system disorders	39	0.00 %
Upper respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	39	0.00 %
Vena cava thrombosis	Vascular disorders	39	0.00 %
Withdrawal bleed	Reproductive system and breast disorders	39	0.00 %
Activated partial thromboplastin time shortened	Investigations	38	0.00 %
Atrial septal defect	Congenital, familial and genetic disorders	38	0.00 %
Auricular swelling	Ear and labyrinth disorders	38	0.00 %
Bacterial vaginosis	Infections and infestations	38	0.00 %
Chest injury	Injury, poisoning and procedural complications	38	0.00 %
Cholangitis	Hepatobiliary disorders	38	0.00 %
Embolism arterial	Vascular disorders	38	0.00 %
Eosinophil count decreased	Investigations	38	0.00 %
External ear pain	Ear and labyrinth disorders	38	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Gastrointestinal necrosis	Gastrointestinal disorders	38	0.00 %
Hair disorder	Skin and subcutaneous tissue disorders	38	0.00 %
Immunosuppression	Immune system disorders	38	0.00 %
Injection site extravasation	General disorders and administration site conditions	38	0.00 %
Inner ear inflammation	Ear and labyrinth disorders	38	0.00 %
Lactose intolerance	Metabolism and nutrition disorders	38	0.00 %
Lymph node abscess	Infections and infestations	38	0.00 %
Microcytic anaemia	Blood and lymphatic system disorders	38	0.00 %
Monocytosis	Blood and lymphatic system disorders	38	0.00 %
Myalgia intercostal	Musculoskeletal and connective tissue disorders	38	0.00 %
Myosclerosis	Musculoskeletal and connective tissue disorders	38	0.00 %
Oesophageal spasm	Gastrointestinal disorders	38	0.00 %
Optic nerve disorder	Eye disorders	38	0.00 %
Paraesthesia ear	Ear and labyrinth disorders	38	0.00 %
Pre-eclampsia	Pregnancy, puerperium and perinatal conditions	38	0.00 %
Proctitis	Gastrointestinal disorders	38	0.00 %
Resuscitation	Surgical and medical procedures	38	0.00 %
Skin temperature	Investigations	38	0.00 %
Transverse sinus thrombosis	Nervous system disorders	38	0.00 %
Acute abdomen	Gastrointestinal disorders	37	0.00 %
Bladder irritation	Renal and urinary disorders	37	0.00 %
Capillary disorder	Vascular disorders	37	0.00 %
Cystitis haemorrhagic	Renal and urinary disorders	37	0.00 %
Drug reaction with eosinophilia and systemic symptoms	Skin and subcutaneous tissue disorders	37	0.00 %
Embolic cerebral infarction	Nervous system disorders	37	0.00 %
Hair colour changes	Skin and subcutaneous tissue disorders	37	0.00 %
Herpes dermatitis	Infections and infestations	37	0.00 %
Herpes zoster cutaneous disseminated	Infections and infestations	37	0.00 %
Hilar lymphadenopathy	Blood and lymphatic system disorders	37	0.00 %
Hyperkeratosis	Skin and subcutaneous tissue disorders	37	0.00 %
Hypertensive urgency	Vascular disorders	37	0.00 %
Hypocalcaemia	Metabolism and nutrition disorders	37	0.00 %
Leukocyturia	Renal and urinary disorders	37	0.00 %
Mean cell haemoglobin concentration decreased	Investigations	37	0.00 %
Metastases to lymph nodes	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	37	0.00 %
Middle ear effusion	Ear and labyrinth disorders	37	0.00 %
Mucosal haemorrhage	General disorders and administration site conditions	37	0.00 %
Pneumonia viral	Infections and infestations	37	0.00 %
Poisoning	Injury, poisoning and procedural complications	37	0.00 %
Postictal state	Nervous system disorders	37	0.00 %
Premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	37	0.00 %
Q fever	Infections and infestations	37	0.00 %
Red cell distribution width increased	Investigations	37	0.00 %
Sputum retention	Respiratory, thoracic and mediastinal disorders	37	0.00 %
Thyroid hormones increased	Investigations	37	0.00 %
Uterine polyp	Reproductive system and breast disorders	37	0.00 %
Vasospasm	Vascular disorders	37	0.00 %
Vocal cord disorder	Respiratory, thoracic and mediastinal disorders	37	0.00 %
Vulvovaginal swelling	Reproductive system and breast disorders	37	0.00 %
Abortion induced	Surgical and medical procedures	36	0.00 %
Allergy to animal	Immune system disorders	36	0.00 %
Anti-neutrophil cytoplasmic antibody positive vasculitis	Immune system disorders	36	0.00 %
Aortic stenosis	Vascular disorders	36	0.00 %
Cardiac ventricular thrombosis	Cardiac disorders	36	0.00 %
Chronic gastritis	Gastrointestinal disorders	36	0.00 %
Chronic sinusitis	Infections and infestations	36	0.00 %
Dental paraesthesia	Gastrointestinal disorders	36	0.00 %
Diverticulum	Gastrointestinal disorders	36	0.00 %
Dyspraxia	Nervous system disorders	36	0.00 %
High density lipoprotein decreased	Investigations	36	0.00 %
Insulin resistance	Metabolism and nutrition disorders	36	0.00 %
Intraventricular haemorrhage	Nervous system disorders	36	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Lower limb fracture	Injury, poisoning and procedural complications	36	0.00 %
Meningioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	36	0.00 %
Mouth injury	Injury, poisoning and procedural complications	36	0.00 %
Paranasal sinus hypersecretion	Respiratory, thoracic and mediastinal disorders	36	0.00 %
Polymyositis	Musculoskeletal and connective tissue disorders	36	0.00 %
Pulseless electrical activity	Cardiac disorders	36	0.00 %
Renal function test abnormal	Investigations	36	0.00 %
Sight disability	Social circumstances	36	0.00 %
Skin atrophy	Skin and subcutaneous tissue disorders	36	0.00 %
Thrombotic cerebral infarction	Nervous system disorders	36	0.00 %
Thrombotic stroke	Nervous system disorders	36	0.00 %
Tongue geographic	Gastrointestinal disorders	36	0.00 %
Trichorrhexis	Skin and subcutaneous tissue disorders	36	0.00 %
Uterine inflammation	Reproductive system and breast disorders	36	0.00 %
Vaccination site dermatitis	General disorders and administration site conditions	36	0.00 %
Vein rupture	Vascular disorders	36	0.00 %
Ventricular dysfunction	Cardiac disorders	36	0.00 %
Abdominal symptom	Gastrointestinal disorders	35	0.00 %
Aortic thrombosis	Vascular disorders	35	0.00 %
Application site pruritus	General disorders and administration site conditions	35	0.00 %
Arteriospasm coronary	Cardiac disorders	35	0.00 %
Clavicle fracture	Injury, poisoning and procedural complications	35	0.00 %
Dermatosis	Skin and subcutaneous tissue disorders	35	0.00 %
Disseminated Bacillus Calmette-Guerin infection	Infections and infestations	35	0.00 %
Femoral neck fracture	Injury, poisoning and procedural complications	35	0.00 %
Foot fracture	Injury, poisoning and procedural complications	35	0.00 %
Gastrointestinal infection	Infections and infestations	35	0.00 %
Granulomatosis with polyangiitis	Vascular disorders	35	0.00 %
Halo vision	Eye disorders	35	0.00 %
Heart valve incompetence	Cardiac disorders	35	0.00 %
Intestinal infarction	Gastrointestinal disorders	35	0.00 %
Lacunar stroke	Nervous system disorders	35	0.00 %
Myofascial pain syndrome	Musculoskeletal and connective tissue disorders	35	0.00 %
Onychoclasis	Skin and subcutaneous tissue disorders	35	0.00 %
Paranasal sinus inflammation	Respiratory, thoracic and mediastinal disorders	35	0.00 %
Peritonsillar abscess	Infections and infestations	35	0.00 %
Prinzmetal angina	Cardiac disorders	35	0.00 %
Prostate cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	35	0.00 %
Protein total increased	Investigations	35	0.00 %
Saliva altered	Gastrointestinal disorders	35	0.00 %
Tachyphrenia	Psychiatric disorders	35	0.00 %
Tongue spasm	Gastrointestinal disorders	35	0.00 %
Upper airway obstruction	Respiratory, thoracic and mediastinal disorders	35	0.00 %
Urticaria papular	Skin and subcutaneous tissue disorders	35	0.00 %
Vaccination site macule	General disorders and administration site conditions	35	0.00 %
Wound secretion	Injury, poisoning and procedural complications	35	0.00 %
Abdominal lymphadenopathy	Blood and lymphatic system disorders	34	0.00 %
Acute hepatic failure	Hepatobiliary disorders	34	0.00 %
Allergy to chemicals	Immune system disorders	34	0.00 %
Angular cheilitis	Gastrointestinal disorders	34	0.00 %
Aortic aneurysm rupture	Vascular disorders	34	0.00 %
Arterial disorder	Vascular disorders	34	0.00 %
Attention deficit hyperactivity disorder	Psychiatric disorders	34	0.00 %
Autoimmune myositis	Musculoskeletal and connective tissue disorders	34	0.00 %
Axillary vein thrombosis	Vascular disorders	34	0.00 %
Defaecation disorder	Gastrointestinal disorders	34	0.00 %
Depression suicidal	Psychiatric disorders	34	0.00 %
Eyelid sensory disorder	Eye disorders	34	0.00 %
Glucose tolerance impaired	Metabolism and nutrition disorders	34	0.00 %
Hypertonic bladder	Renal and urinary disorders	34	0.00 %
Injection site joint pain	General disorders and administration site conditions	34	0.00 %
Injection site movement impairment	General disorders and administration site conditions	34	0.00 %
Maculopathy	Eye disorders	34	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Magnetic resonance imaging abnormal	Investigations	34	0.00 %
Marasmus	Metabolism and nutrition disorders	34	0.00 %
Mean cell volume increased	Investigations	34	0.00 %
Palmar-plantar erythrodysesthesia syndrome	Skin and subcutaneous tissue disorders	34	0.00 %
Peripheral motor neuropathy	Nervous system disorders	34	0.00 %
Peripheral paralysis	Nervous system disorders	34	0.00 %
Pleocytosis	Nervous system disorders	34	0.00 %
Potentiating drug interaction	General disorders and administration site conditions	34	0.00 %
Product packaging quantity issue	Product issues	34	0.00 %
Sexual dysfunction	Reproductive system and breast disorders	34	0.00 %
Subdural haemorrhage	Injury, poisoning and procedural complications	34	0.00 %
Superinfection bacterial	Infections and infestations	34	0.00 %
Vaccination site plaque	General disorders and administration site conditions	34	0.00 %
Vulval haemorrhage	Reproductive system and breast disorders	34	0.00 %
Acute febrile neutrophilic dermatosis	Skin and subcutaneous tissue disorders	33	0.00 %
Agranulocytosis	Blood and lymphatic system disorders	33	0.00 %
Blood chloride increased	Investigations	33	0.00 %
Blood folate decreased	Investigations	33	0.00 %
Brain herniation	Injury, poisoning and procedural complications	33	0.00 %
Circumoral oedema	Skin and subcutaneous tissue disorders	33	0.00 %
Ileus paralytic	Gastrointestinal disorders	33	0.00 %
Increased insulin requirement	Metabolism and nutrition disorders	33	0.00 %
Laryngeal inflammation	Respiratory, thoracic and mediastinal disorders	33	0.00 %
Ligament pain	Musculoskeletal and connective tissue disorders	33	0.00 %
Mean cell volume decreased	Investigations	33	0.00 %
Microangiopathy	Vascular disorders	33	0.00 %
Mite allergy	Immune system disorders	33	0.00 %
Oral mucosal exfoliation	Gastrointestinal disorders	33	0.00 %
Palatal disorder	Gastrointestinal disorders	33	0.00 %
Pelvic inflammatory disease	Infections and infestations	33	0.00 %
Perioral dermatitis	Skin and subcutaneous tissue disorders	33	0.00 %
Plasma cell myeloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	33	0.00 %
Platelet count abnormal	Investigations	33	0.00 %
Polyserositis	General disorders and administration site conditions	33	0.00 %
Pre-existing disease	General disorders and administration site conditions	33	0.00 %
Procalcitonin increased	Investigations	33	0.00 %
Putamen haemorrhage	Nervous system disorders	33	0.00 %
Shock symptom	Vascular disorders	33	0.00 %
Thermal burns of eye	Injury, poisoning and procedural complications	33	0.00 %
Thirst decreased	General disorders and administration site conditions	33	0.00 %
Trichoglossia	Gastrointestinal disorders	33	0.00 %
White blood cell count abnormal	Investigations	33	0.00 %
Accidental underdose	Injury, poisoning and procedural complications	32	0.00 %
Akinesia	Nervous system disorders	32	0.00 %
Allergic cough	Respiratory, thoracic and mediastinal disorders	32	0.00 %
Anti-thyroid antibody increased	Investigations	32	0.00 %
Basilar artery thrombosis	Nervous system disorders	32	0.00 %
Brachial plexopathy	Nervous system disorders	32	0.00 %
Clostridium difficile infection	Infections and infestations	32	0.00 %
Concomitant disease progression	General disorders and administration site conditions	32	0.00 %
Conjunctival oedema	Eye disorders	32	0.00 %
Cor pulmonale acute	Cardiac disorders	32	0.00 %
Creutzfeldt-Jakob disease	Infections and infestations	32	0.00 %
Cytokine storm	Immune system disorders	32	0.00 %
Dandruff	Skin and subcutaneous tissue disorders	32	0.00 %
Discoloured vomit	Gastrointestinal disorders	32	0.00 %
Discouragement	Psychiatric disorders	32	0.00 %
Dissociative disorder	Psychiatric disorders	32	0.00 %
Drowning	General disorders and administration site conditions	32	0.00 %
Generalised anxiety disorder	Psychiatric disorders	32	0.00 %
Glare	Eye disorders	32	0.00 %
Injection site hypersensitivity	General disorders and administration site conditions	32	0.00 %
Intussusception	Gastrointestinal disorders	32	0.00 %
IVth nerve paralysis	Nervous system disorders	32	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Mean cell haemoglobin decreased	Investigations	32	0.00 %
Pregnancy	Pregnancy, puerperium and perinatal conditions	32	0.00 %
Prothrombin time shortened	Investigations	32	0.00 %
Pyelonephritis acute	Infections and infestations	32	0.00 %
Scleroderma	Musculoskeletal and connective tissue disorders	32	0.00 %
Severe acute respiratory syndrome	Infections and infestations	32	0.00 %
Sinonasal obstruction	Respiratory, thoracic and mediastinal disorders	32	0.00 %
Systolic hypertension	Vascular disorders	32	0.00 %
Tendon injury	Injury, poisoning and procedural complications	32	0.00 %
Tongue rough	Gastrointestinal disorders	32	0.00 %
Anaemia macrocytic	Blood and lymphatic system disorders	31	0.00 %
Animal bite	Injury, poisoning and procedural complications	31	0.00 %
Anti-thyroid antibody positive	Investigations	31	0.00 %
Artery dissection	Vascular disorders	31	0.00 %
Atonic seizures	Nervous system disorders	31	0.00 %
Borrelia infection	Infections and infestations	31	0.00 %
Cardiovascular symptom	Cardiac disorders	31	0.00 %
Circadian rhythm sleep disorder	Nervous system disorders	31	0.00 %
Colon cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	31	0.00 %
Diabetic metabolic decompensation	Metabolism and nutrition disorders	31	0.00 %
Eustachian tube obstruction	Ear and labyrinth disorders	31	0.00 %
Genital herpes zoster	Infections and infestations	31	0.00 %
Genital swelling	Reproductive system and breast disorders	31	0.00 %
Hypervigilance	Psychiatric disorders	31	0.00 %
Incorrect dosage administered	Injury, poisoning and procedural complications	31	0.00 %
International normalised ratio abnormal	Investigations	31	0.00 %
Joint instability	Musculoskeletal and connective tissue disorders	31	0.00 %
Left atrial enlargement	Cardiac disorders	31	0.00 %
Lip exfoliation	Gastrointestinal disorders	31	0.00 %
Lip haemorrhage	Gastrointestinal disorders	31	0.00 %
Metabolic disorder	Metabolism and nutrition disorders	31	0.00 %
Middle ear inflammation	Ear and labyrinth disorders	31	0.00 %
Neuromyopathy	Nervous system disorders	31	0.00 %
Optic neuropathy	Eye disorders	31	0.00 %
Parapsoriasis	Skin and subcutaneous tissue disorders	31	0.00 %
Penile pain	Reproductive system and breast disorders	31	0.00 %
Penis disorder	Reproductive system and breast disorders	31	0.00 %
Pericardial fibrosis	Cardiac disorders	31	0.00 %
Polycythaemia	Blood and lymphatic system disorders	31	0.00 %
Product supply issue	Product issues	31	0.00 %
Pupillary reflex impaired	Eye disorders	31	0.00 %
Retinal vascular occlusion	Eye disorders	31	0.00 %
Right ventricular dysfunction	Cardiac disorders	31	0.00 %
Skin wound	Injury, poisoning and procedural complications	31	0.00 %
Sudden visual loss	Eye disorders	31	0.00 %
Superficial vein prominence	Vascular disorders	31	0.00 %
Thyrotoxic crisis	Endocrine disorders	31	0.00 %
Tonsillar erythema	Respiratory, thoracic and mediastinal disorders	31	0.00 %
Tumour marker increased	Investigations	31	0.00 %
Urinary bladder haemorrhage	Renal and urinary disorders	31	0.00 %
Urine output increased	Investigations	31	0.00 %
Acarodermatitis	Infections and infestations	30	0.00 %
Adjustment disorder with depressed mood	Psychiatric disorders	30	0.00 %
Autonomic neuropathy	Nervous system disorders	30	0.00 %
Basal ganglia haemorrhage	Nervous system disorders	30	0.00 %
Blood creatine phosphokinase decreased	Investigations	30	0.00 %
Bone contusion	Injury, poisoning and procedural complications	30	0.00 %
Burning feet syndrome	Nervous system disorders	30	0.00 %
Burnout syndrome	Psychiatric disorders	30	0.00 %
Central pain syndrome	Nervous system disorders	30	0.00 %
Cholecystitis acute	Hepatobiliary disorders	30	0.00 %
Collagen disorder	Musculoskeletal and connective tissue disorders	30	0.00 %
Electrocardiogram change	Investigations	30	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Eosinophilic pneumonia	Respiratory, thoracic and mediastinal disorders	30	0.00 %
Essential tremor	Nervous system disorders	30	0.00 %
Eustachian tube dysfunction	Ear and labyrinth disorders	30	0.00 %
Frostbite	Injury, poisoning and procedural complications	30	0.00 %
Gingival erythema	Gastrointestinal disorders	30	0.00 %
Gluten sensitivity	Metabolism and nutrition disorders	30	0.00 %
Haemangioma of skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	30	0.00 %
Hyperphagia	Metabolism and nutrition disorders	30	0.00 %
Juvenile idiopathic arthritis	Musculoskeletal and connective tissue disorders	30	0.00 %
Lung consolidation	Respiratory, thoracic and mediastinal disorders	30	0.00 %
Multiple injuries	Injury, poisoning and procedural complications	30	0.00 %
Negative thoughts	Psychiatric disorders	30	0.00 %
Pelvic discomfort	Reproductive system and breast disorders	30	0.00 %
Pulmonary arterial hypertension	Respiratory, thoracic and mediastinal disorders	30	0.00 %
Pustular psoriasis	Skin and subcutaneous tissue disorders	30	0.00 %
Retinal artery thrombosis	Eye disorders	30	0.00 %
Retrograde amnesia	Nervous system disorders	30	0.00 %
Reversed hot-cold sensation	Nervous system disorders	30	0.00 %
Sacroiliitis	Musculoskeletal and connective tissue disorders	30	0.00 %
Serum sickness	Immune system disorders	30	0.00 %
Thrombotic microangiopathy	Blood and lymphatic system disorders	30	0.00 %
Amaurosis	Eye disorders	29	0.00 %
Amyotrophy	Musculoskeletal and connective tissue disorders	29	0.00 %
Anorectal discomfort	Gastrointestinal disorders	29	0.00 %
Aortic valve stenosis	Cardiac disorders	29	0.00 %
Autoantibody positive	Investigations	29	0.00 %
Corneal graft rejection	Immune system disorders	29	0.00 %
Cranial nerve paralysis	Nervous system disorders	29	0.00 %
Cytomegalovirus test positive	Investigations	29	0.00 %
Gastrointestinal hypermotility	Gastrointestinal disorders	29	0.00 %
Gastrointestinal tract irritation	Gastrointestinal disorders	29	0.00 %
Hearing disability	Social circumstances	29	0.00 %
Hyperuricaemia	Metabolism and nutrition disorders	29	0.00 %
Inhibitory drug interaction	General disorders and administration site conditions	29	0.00 %
Injury associated with device	General disorders and administration site conditions	29	0.00 %
Klebsiella infection	Infections and infestations	29	0.00 %
Mixed anxiety and depressive disorder	Psychiatric disorders	29	0.00 %
Mononeuritis	Nervous system disorders	29	0.00 %
Muscle oedema	Musculoskeletal and connective tissue disorders	29	0.00 %
Myocardial necrosis	Cardiac disorders	29	0.00 %
Nipple disorder	Reproductive system and breast disorders	29	0.00 %
Ophthalmic herpes simplex	Infections and infestations	29	0.00 %
Oropharyngeal oedema	Respiratory, thoracic and mediastinal disorders	29	0.00 %
Pancreatic carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	29	0.00 %
Sinus node dysfunction	Cardiac disorders	29	0.00 %
Sputum abnormal	Investigations	29	0.00 %
Trigeminal neuritis	Nervous system disorders	29	0.00 %
Uterine hypertonus	Pregnancy, puerperium and perinatal conditions	29	0.00 %
Vaccination site joint discomfort	General disorders and administration site conditions	29	0.00 %
Vascular headache	Nervous system disorders	29	0.00 %
Visual brightness	Eye disorders	29	0.00 %
Administration site oedema	General disorders and administration site conditions	28	0.00 %
Astigmatism	Eye disorders	28	0.00 %
Blood iron increased	Investigations	28	0.00 %
Blood loss anaemia	Blood and lymphatic system disorders	28	0.00 %
Breast feeding	Social circumstances	28	0.00 %
Chromatopsia	Eye disorders	28	0.00 %
Extraocular muscle paresis	Eye disorders	28	0.00 %
Extrapyramidal disorder	Nervous system disorders	28	0.00 %
Hallucinations, mixed	Psychiatric disorders	28	0.00 %
Helicobacter infection	Infections and infestations	28	0.00 %
Hypovitaminosis	Metabolism and nutrition disorders	28	0.00 %
Inguinal hernia	Gastrointestinal disorders	28	0.00 %
Intra-abdominal haemorrhage	Gastrointestinal disorders	28	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Job dissatisfaction	Social circumstances	28	0.00 %
Ketoacidosis	Metabolism and nutrition disorders	28	0.00 %
Pancreatic disorder	Gastrointestinal disorders	28	0.00 %
Pericardial rub	Cardiac disorders	28	0.00 %
Pernio-like erythema	Skin and subcutaneous tissue disorders	28	0.00 %
Persistent postural-perceptual dizziness	Nervous system disorders	28	0.00 %
Pneumothorax spontaneous	Respiratory, thoracic and mediastinal disorders	28	0.00 %
Preterm premature rupture of membranes	Pregnancy, puerperium and perinatal conditions	28	0.00 %
Purulent discharge	Infections and infestations	28	0.00 %
Stiff tongue	Gastrointestinal disorders	28	0.00 %
Superinfection	Infections and infestations	28	0.00 %
Visual analogue scale	Investigations	28	0.00 %
Administration site erythema	General disorders and administration site conditions	27	0.00 %
Arteritis	Vascular disorders	27	0.00 %
Arthritis infective	Infections and infestations	27	0.00 %
Axonal neuropathy	Nervous system disorders	27	0.00 %
Basal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	27	0.00 %
Bite	Injury, poisoning and procedural complications	27	0.00 %
Blood chloride decreased	Investigations	27	0.00 %
Cerebellar syndrome	Nervous system disorders	27	0.00 %
Completed suicide	Psychiatric disorders	27	0.00 %
Conjunctival irritation	Eye disorders	27	0.00 %
Decreased vibratory sense	Nervous system disorders	27	0.00 %
Eczema asteatotic	Skin and subcutaneous tissue disorders	27	0.00 %
Electrocardiogram normal	Investigations	27	0.00 %
Electrocardiogram ST segment abnormal	Investigations	27	0.00 %
Encephalitis viral	Infections and infestations	27	0.00 %
Endocrine ophthalmopathy	Eye disorders	27	0.00 %
Escherichia infection	Infections and infestations	27	0.00 %
Exertional headache	Nervous system disorders	27	0.00 %
Exostosis	Musculoskeletal and connective tissue disorders	27	0.00 %
Extremity contracture	Musculoskeletal and connective tissue disorders	27	0.00 %
Eye symptom	Eye disorders	27	0.00 %
Hepatitis cholestatic	Hepatobiliary disorders	27	0.00 %
Hepatosplenomegaly	Hepatobiliary disorders	27	0.00 %
Herpes zoster meningoencephalitis	Infections and infestations	27	0.00 %
Hypercalcaemia	Metabolism and nutrition disorders	27	0.00 %
Hypertriglyceridaemia	Metabolism and nutrition disorders	27	0.00 %
Labile hypertension	Vascular disorders	27	0.00 %
Limbic encephalitis	Nervous system disorders	27	0.00 %
Meningeal disorder	Nervous system disorders	27	0.00 %
Mumps	Infections and infestations	27	0.00 %
Obstruction	General disorders and administration site conditions	27	0.00 %
Ocular myasthenia	Eye disorders	27	0.00 %
Optic nerve injury	Injury, poisoning and procedural complications	27	0.00 %
Paronychia	Infections and infestations	27	0.00 %
Phantom limb syndrome	Nervous system disorders	27	0.00 %
Premature menarche	Endocrine disorders	27	0.00 %
Premature ovulation	Reproductive system and breast disorders	27	0.00 %
Procedural pain	Injury, poisoning and procedural complications	27	0.00 %
Puncture site bruise	General disorders and administration site conditions	27	0.00 %
Rectal tenesmus	Gastrointestinal disorders	27	0.00 %
Reflexes abnormal	Nervous system disorders	27	0.00 %
Sensitivity to weather change	General disorders and administration site conditions	27	0.00 %
Tooth extraction	Surgical and medical procedures	27	0.00 %
Urine flow decreased	Renal and urinary disorders	27	0.00 %
Abdominal mass	Gastrointestinal disorders	26	0.00 %
Acute leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	26	0.00 %
Administration site bruise	General disorders and administration site conditions	26	0.00 %
Administration site reaction	General disorders and administration site conditions	26	0.00 %
Analgesic therapy	Surgical and medical procedures	26	0.00 %
Arthritis bacterial	Infections and infestations	26	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Atopy	Immune system disorders	26	0.00 %
Basophil count increased	Investigations	26	0.00 %
Benign prostatic hyperplasia	Reproductive system and breast disorders	26	0.00 %
Breast haematoma	Reproductive system and breast disorders	26	0.00 %
Coagulation time prolonged	Investigations	26	0.00 %
Encephalomyelitis	Infections and infestations	26	0.00 %
Eosinophilic granulomatosis with polyangiitis	Immune system disorders	26	0.00 %
Epstein-Barr virus antibody positive	Investigations	26	0.00 %
Essential hypertension	Vascular disorders	26	0.00 %
Genital herpes simplex	Infections and infestations	26	0.00 %
Glomerulonephritis rapidly progressive	Renal and urinary disorders	26	0.00 %
Hepatocellular injury	Hepatobiliary disorders	26	0.00 %
Hyperferritinæmia	Metabolism and nutrition disorders	26	0.00 %
Infertility female	Reproductive system and breast disorders	26	0.00 %
Infusion related reaction	Injury, poisoning and procedural complications	26	0.00 %
Injection site lymphadenopathy	General disorders and administration site conditions	26	0.00 %
Macroglossia	Congenital, familial and genetic disorders	26	0.00 %
Oral mucosa erosion	Gastrointestinal disorders	26	0.00 %
Pelvic fracture	Injury, poisoning and procedural complications	26	0.00 %
Periodontitis	Infections and infestations	26	0.00 %
Postpartum haemorrhage	Pregnancy, puerperium and perinatal conditions	26	0.00 %
Radial pulse abnormal	Investigations	26	0.00 %
Right ventricular dilatation	Cardiac disorders	26	0.00 %
Scoliosis	Musculoskeletal and connective tissue disorders	26	0.00 %
Systolic dysfunction	Cardiac disorders	26	0.00 %
Temperature difference of extremities	Investigations	26	0.00 %
Tympanic membrane perforation	Ear and labyrinth disorders	26	0.00 %
Urinary tract pain	Renal and urinary disorders	26	0.00 %
Uterine disorder	Reproductive system and breast disorders	26	0.00 %
Weight fluctuation	Metabolism and nutrition disorders	26	0.00 %
Adrenal disorder	Endocrine disorders	25	0.00 %
Anal sphincter atony	Gastrointestinal disorders	25	0.00 %
Antibody test negative	Investigations	25	0.00 %
Arterial stenosis	Vascular disorders	25	0.00 %
Azotaemia	Renal and urinary disorders	25	0.00 %
Bipolar disorder	Psychiatric disorders	25	0.00 %
Bladder dysfunction	Renal and urinary disorders	25	0.00 %
Blood follicle stimulating hormone increased	Investigations	25	0.00 %
Blood magnesium decreased	Investigations	25	0.00 %
Bone marrow oedema	Blood and lymphatic system disorders	25	0.00 %
Bone neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	25	0.00 %
Brain stem stroke	Nervous system disorders	25	0.00 %
Burns second degree	Injury, poisoning and procedural complications	25	0.00 %
Cerebellar ataxia	Nervous system disorders	25	0.00 %
Cytomegalovirus infection reactivation	Infections and infestations	25	0.00 %
Deformity	General disorders and administration site conditions	25	0.00 %
Device connection issue	Product issues	25	0.00 %
Dysacusis	Ear and labyrinth disorders	25	0.00 %
Excessive eye blinking	Eye disorders	25	0.00 %
Faecal calprotectin increased	Investigations	25	0.00 %
Faeces hard	Gastrointestinal disorders	25	0.00 %
Fasciitis	Musculoskeletal and connective tissue disorders	25	0.00 %
Haemorrhagic transformation stroke	Nervous system disorders	25	0.00 %
Hyperresponsive to stimuli	Nervous system disorders	25	0.00 %
Intentional dose omission	Injury, poisoning and procedural complications	25	0.00 %
Left ventricular dilatation	Cardiac disorders	25	0.00 %
Lipoedema	Metabolism and nutrition disorders	25	0.00 %
Magnetic resonance imaging head abnormal	Investigations	25	0.00 %
Monocyte count decreased	Investigations	25	0.00 %
Muscle mass	Musculoskeletal and connective tissue disorders	25	0.00 %
Neck injury	Injury, poisoning and procedural complications	25	0.00 %
Neuromuscular pain	Nervous system disorders	25	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Obesity	Metabolism and nutrition disorders	25	0.00 %
Onychomadesis	Skin and subcutaneous tissue disorders	25	0.00 %
Pelvic haemorrhage	Reproductive system and breast disorders	25	0.00 %
Penile swelling	Reproductive system and breast disorders	25	0.00 %
Personality disorder	Psychiatric disorders	25	0.00 %
Premature separation of placenta	Pregnancy, puerperium and perinatal conditions	25	0.00 %
Product physical issue	Product issues	25	0.00 %
Retinal disorder	Eye disorders	25	0.00 %
Sensory overload	Nervous system disorders	25	0.00 %
Sickle cell anaemia with crisis	Blood and lymphatic system disorders	25	0.00 %
Staphylococcal bacteraemia	Infections and infestations	25	0.00 %
Thyroid cyst	Endocrine disorders	25	0.00 %
Tonsillitis bacterial	Infections and infestations	25	0.00 %
Toxic epidermal necrolysis	Skin and subcutaneous tissue disorders	25	0.00 %
Tracheal pain	Respiratory, thoracic and mediastinal disorders	25	0.00 %
Tuberculosis	Infections and infestations	25	0.00 %
Vagus nerve disorder	Nervous system disorders	25	0.00 %
Vitreous opacities	Eye disorders	25	0.00 %
Wound infection	Infections and infestations	25	0.00 %
Alopecia totalis	Skin and subcutaneous tissue disorders	24	0.00 %
Anal pruritus	Gastrointestinal disorders	24	0.00 %
Anembryonic gestation	Pregnancy, puerperium and perinatal conditions	24	0.00 %
Anhedonia	Psychiatric disorders	24	0.00 %
Ankle fracture	Injury, poisoning and procedural complications	24	0.00 %
Blood immunoglobulin G decreased	Investigations	24	0.00 %
Breath sounds	Investigations	24	0.00 %
Bronchitis chronic	Respiratory, thoracic and mediastinal disorders	24	0.00 %
Cardiac aneurysm	Cardiac disorders	24	0.00 %
Central nervous system vasculitis	Nervous system disorders	24	0.00 %
Cerebral small vessel ischaemic disease	Nervous system disorders	24	0.00 %
Corneal disorder	Eye disorders	24	0.00 %
Corneal reflex decreased	Investigations	24	0.00 %
CSF cell count increased	Investigations	24	0.00 %
Cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	24	0.00 %
Cystitis interstitial	Renal and urinary disorders	24	0.00 %
Diabetes insipidus	Endocrine disorders	24	0.00 %
Febrile neutropenia	Blood and lymphatic system disorders	24	0.00 %
Gastric pH decreased	Investigations	24	0.00 %
Gravitational oedema	General disorders and administration site conditions	24	0.00 %
Herpes zoster infection neurological	Infections and infestations	24	0.00 %
Hydronephrosis	Renal and urinary disorders	24	0.00 %
Hypermetropia	Eye disorders	24	0.00 %
International normalised ratio fluctuation	Investigations	24	0.00 %
Itching scar	Skin and subcutaneous tissue disorders	24	0.00 %
Jugular vein distension	Vascular disorders	24	0.00 %
Lymphocyte percentage decreased	Investigations	24	0.00 %
Measles	Infections and infestations	24	0.00 %
Meningitis bacterial	Infections and infestations	24	0.00 %
Microscopic polyangiitis	Vascular disorders	24	0.00 %
Mononeuropathy	Nervous system disorders	24	0.00 %
Multi-organ disorder	General disorders and administration site conditions	24	0.00 %
Nasal mucosal disorder	Respiratory, thoracic and mediastinal disorders	24	0.00 %
Neutrophil percentage increased	Investigations	24	0.00 %
Oligoarthritis	Musculoskeletal and connective tissue disorders	24	0.00 %
Peripheral nerve lesion	Nervous system disorders	24	0.00 %
Pseudolymphoma	Blood and lymphatic system disorders	24	0.00 %
Psychomotor retardation	Psychiatric disorders	24	0.00 %
Purulence	Infections and infestations	24	0.00 %
Rheumatoid factor positive	Investigations	24	0.00 %
Scrotal swelling	Reproductive system and breast disorders	24	0.00 %
Self esteem decreased	Psychiatric disorders	24	0.00 %
Sleep attacks	Psychiatric disorders	24	0.00 %
Solar dermatitis	Skin and subcutaneous tissue disorders	24	0.00 %
Submaxillary gland enlargement	Gastrointestinal disorders	24	0.00 %
Transient aphasia	Nervous system disorders	24	0.00 %
Transplant rejection	Immune system disorders	24	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Tympanic membrane disorder	Ear and labyrinth disorders	24	0.00 %
Aortic dilatation	Vascular disorders	23	0.00 %
Atrial thrombosis	Cardiac disorders	23	0.00 %
Autoimmune arthritis	Musculoskeletal and connective tissue disorders	23	0.00 %
Blister infected	Infections and infestations	23	0.00 %
Bronchiolitis	Infections and infestations	23	0.00 %
Bronchopneumopathy	Respiratory, thoracic and mediastinal disorders	23	0.00 %
C-reactive protein decreased	Investigations	23	0.00 %
Cerebral artery stenosis	Nervous system disorders	23	0.00 %
Chondrocalcinosis	Musculoskeletal and connective tissue disorders	23	0.00 %
Conduction disorder	Cardiac disorders	23	0.00 %
Dermatitis infected	Infections and infestations	23	0.00 %
Drug exposure before pregnancy	Injury, poisoning and procedural complications	23	0.00 %
Eating disorder symptom	Metabolism and nutrition disorders	23	0.00 %
Echocardiogram	Investigations	23	0.00 %
Electrocardiogram T wave abnormal	Investigations	23	0.00 %
Enterocolitis haemorrhagic	Gastrointestinal disorders	23	0.00 %
Erection increased	Reproductive system and breast disorders	23	0.00 %
Erythema annulare	Skin and subcutaneous tissue disorders	23	0.00 %
Erythromelalgia	Vascular disorders	23	0.00 %
Extensor plantar response	Nervous system disorders	23	0.00 %
Eye colour change	Eye disorders	23	0.00 %
Eyelid infection	Infections and infestations	23	0.00 %
Fibrosis	General disorders and administration site conditions	23	0.00 %
Glioblastoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	23	0.00 %
Granuloma	General disorders and administration site conditions	23	0.00 %
Haemorrhagic cerebral infarction	Nervous system disorders	23	0.00 %
Hodgkin's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	23	0.00 %
Hypersensitivity pneumonitis	Respiratory, thoracic and mediastinal disorders	23	0.00 %
Hypotensive crisis	Vascular disorders	23	0.00 %
Idiopathic pulmonary fibrosis	Respiratory, thoracic and mediastinal disorders	23	0.00 %
Intentional self-harm	Psychiatric disorders	23	0.00 %
Intervertebral discitis	Infections and infestations	23	0.00 %
Intestinal perforation	Gastrointestinal disorders	23	0.00 %
Ischaemic cardiomyopathy	Cardiac disorders	23	0.00 %
Limb deformity	Musculoskeletal and connective tissue disorders	23	0.00 %
Metastases to liver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	23	0.00 %
Myoglobin blood increased	Investigations	23	0.00 %
Neoplasm skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	23	0.00 %
Neovascular age-related macular degeneration	Eye disorders	23	0.00 %
Noninfective ophoritis	Reproductive system and breast disorders	23	0.00 %
Oxygen consumption decreased	Investigations	23	0.00 %
Periorbital haematoma	Injury, poisoning and procedural complications	23	0.00 %
Product dispensing error	Injury, poisoning and procedural complications	23	0.00 %
Pulmonary sarcoidosis	Respiratory, thoracic and mediastinal disorders	23	0.00 %
Retinal exudates	Eye disorders	23	0.00 %
Retinal oedema	Eye disorders	23	0.00 %
Type III immune complex mediated reaction	Immune system disorders	23	0.00 %
Vaginal ulceration	Reproductive system and breast disorders	23	0.00 %
Varicella virus test positive	Investigations	23	0.00 %
Visual snow syndrome	Eye disorders	23	0.00 %
Wheelchair user	Social circumstances	23	0.00 %
Allergic respiratory symptom	Respiratory, thoracic and mediastinal disorders	22	0.00 %
Alopecia universalis	Skin and subcutaneous tissue disorders	22	0.00 %
Antiphospholipid antibodies positive	Investigations	22	0.00 %
Application site movement impairment	General disorders and administration site conditions	22	0.00 %
Atrophy	General disorders and administration site conditions	22	0.00 %
Balanoposthitis	Reproductive system and breast disorders	22	0.00 %
Bicytopenia	Blood and lymphatic system disorders	22	0.00 %
Bladder spasm	Renal and urinary disorders	22	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Blood bicarbonate decreased	Investigations	22	0.00 %
Blood calcium increased	Investigations	22	0.00 %
Blood phosphorus decreased	Investigations	22	0.00 %
Brain stem syndrome	Nervous system disorders	22	0.00 %
Chest crushing	Injury, poisoning and procedural complications	22	0.00 %
Chorea	Nervous system disorders	22	0.00 %
Convulsions local	Nervous system disorders	22	0.00 %
Coronary artery dissection	Cardiac disorders	22	0.00 %
Dyslexia	Nervous system disorders	22	0.00 %
Dyspareunia	Reproductive system and breast disorders	22	0.00 %
Dyspnoea paroxysmal nocturnal	Respiratory, thoracic and mediastinal disorders	22	0.00 %
Electrocardiogram PR segment depression	Investigations	22	0.00 %
Electrocardiogram QRS complex shortened	Investigations	22	0.00 %
Exposure via eye contact	Injury, poisoning and procedural complications	22	0.00 %
Fear of falling	Psychiatric disorders	22	0.00 %
Fixed eruption	Skin and subcutaneous tissue disorders	22	0.00 %
Habit cough	Psychiatric disorders	22	0.00 %
Haemoglobin abnormal	Investigations	22	0.00 %
Helplessness	Psychiatric disorders	22	0.00 %
Horner's syndrome	Nervous system disorders	22	0.00 %
Humerus fracture	Injury, poisoning and procedural complications	22	0.00 %
Hypoperfusion	Vascular disorders	22	0.00 %
Impaired self-care	General disorders and administration site conditions	22	0.00 %
Intentional product misuse	Injury, poisoning and procedural complications	22	0.00 %
Kawasaki's disease	Vascular disorders	22	0.00 %
Loose tooth	Gastrointestinal disorders	22	0.00 %
Lupus-like syndrome	Musculoskeletal and connective tissue disorders	22	0.00 %
Mean cell haemoglobin increased	Investigations	22	0.00 %
Microembolism	Vascular disorders	22	0.00 %
Motor neurone disease	Nervous system disorders	22	0.00 %
Muscle haemorrhage	Musculoskeletal and connective tissue disorders	22	0.00 %
Nasal crusting	Respiratory, thoracic and mediastinal disorders	22	0.00 %
Neuritis cranial	Nervous system disorders	22	0.00 %
Non-Hodgkin's lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22	0.00 %
Onychalgia	Skin and subcutaneous tissue disorders	22	0.00 %
Onycholysis	Skin and subcutaneous tissue disorders	22	0.00 %
Oropharyngeal spasm	Respiratory, thoracic and mediastinal disorders	22	0.00 %
Osteopenia	Musculoskeletal and connective tissue disorders	22	0.00 %
Ovarian disorder	Reproductive system and breast disorders	22	0.00 %
Pharyngeal stenosis	Respiratory, thoracic and mediastinal disorders	22	0.00 %
Pneumonia pneumococcal	Infections and infestations	22	0.00 %
Protein C increased	Investigations	22	0.00 %
Pulmonary arterial pressure increased	Investigations	22	0.00 %
Pupil fixed	Eye disorders	22	0.00 %
Schizophrenia	Psychiatric disorders	22	0.00 %
Spleen disorder	Blood and lymphatic system disorders	22	0.00 %
Splenic vein thrombosis	Blood and lymphatic system disorders	22	0.00 %
Testicular disorder	Reproductive system and breast disorders	22	0.00 %
Unintended pregnancy	Pregnancy, puerperium and perinatal conditions	22	0.00 %
Urinary hesitation	Renal and urinary disorders	22	0.00 %
Urine ketone body present	Investigations	22	0.00 %
Vaccination site necrosis	General disorders and administration site conditions	22	0.00 %
Vaginal odour	Reproductive system and breast disorders	22	0.00 %
Ventricular hypertrophy	Cardiac disorders	22	0.00 %
Vertigo labyrinthine	Ear and labyrinth disorders	22	0.00 %
Vitamin B12 increased	Investigations	22	0.00 %
Vitreous disorder	Eye disorders	22	0.00 %
Abscess oral	Infections and infestations	21	0.00 %
Blood oestrogen increased	Investigations	21	0.00 %
Blood prolactin increased	Investigations	21	0.00 %
Blood urea decreased	Investigations	21	0.00 %
Breast milk discolouration	Reproductive system and breast disorders	21	0.00 %
Bronchostenosis	Respiratory, thoracic and mediastinal disorders	21	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Burn oral cavity	Injury, poisoning and procedural complications	21	0.00 %
Bursa disorder	Musculoskeletal and connective tissue disorders	21	0.00 %
Cardiospasm	Gastrointestinal disorders	21	0.00 %
Congestive hepatopathy	Hepatobiliary disorders	21	0.00 %
Diaphragmatic disorder	Respiratory, thoracic and mediastinal disorders	21	0.00 %
Enanthema	General disorders and administration site conditions	21	0.00 %
Gangrene	Infections and infestations	21	0.00 %
Gastrointestinal oedema	Gastrointestinal disorders	21	0.00 %
Gouty arthritis	Musculoskeletal and connective tissue disorders	21	0.00 %
Haemorrhagic infarction	Vascular disorders	21	0.00 %
Hypertrichosis	Skin and subcutaneous tissue disorders	21	0.00 %
IIIrd nerve paresis	Nervous system disorders	21	0.00 %
Laryngeal obstruction	Respiratory, thoracic and mediastinal disorders	21	0.00 %
Ligament rupture	Injury, poisoning and procedural complications	21	0.00 %
Lymphocyte morphology abnormal	Investigations	21	0.00 %
Mesenteric artery thrombosis	Gastrointestinal disorders	21	0.00 %
Mononeuropathy multiplex	Nervous system disorders	21	0.00 %
Myasthenic syndrome	Nervous system disorders	21	0.00 %
Myocardial rupture	Cardiac disorders	21	0.00 %
Nasal injury	Injury, poisoning and procedural complications	21	0.00 %
Neoplasm recurrence	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21	0.00 %
Neutrophil count abnormal	Investigations	21	0.00 %
No reaction on previous exposure to drug	General disorders and administration site conditions	21	0.00 %
Oral infection	Infections and infestations	21	0.00 %
Otitis media acute	Infections and infestations	21	0.00 %
Otolithiasis	Ear and labyrinth disorders	21	0.00 %
Paraesthesia mucosal	Nervous system disorders	21	0.00 %
Peripheral sensorimotor neuropathy	Nervous system disorders	21	0.00 %
Pharyngeal haemorrhage	Respiratory, thoracic and mediastinal disorders	21	0.00 %
Post vaccination syndrome	Injury, poisoning and procedural complications	21	0.00 %
Product label issue	Product issues	21	0.00 %
Pulse volume decreased	Investigations	21	0.00 %
Resting tremor	Nervous system disorders	21	0.00 %
Skin striae	Skin and subcutaneous tissue disorders	21	0.00 %
Skin texture abnormal	Skin and subcutaneous tissue disorders	21	0.00 %
Soft tissue infection	Infections and infestations	21	0.00 %
Therapeutic response shortened	General disorders and administration site conditions	21	0.00 %
Thoracic outlet syndrome	Nervous system disorders	21	0.00 %
Thyroxine increased	Investigations	21	0.00 %
Tourette's disorder	Congenital, familial and genetic disorders	21	0.00 %
Traumatic haematoma	Injury, poisoning and procedural complications	21	0.00 %
Typical aura without headache	Nervous system disorders	21	0.00 %
Ulnar nerve injury	Injury, poisoning and procedural complications	21	0.00 %
Urethral pain	Renal and urinary disorders	21	0.00 %
Vaccination site dryness	General disorders and administration site conditions	21	0.00 %
Vibratory sense increased	Nervous system disorders	21	0.00 %
Vulvovaginal inflammation	Reproductive system and breast disorders	21	0.00 %
Wrist fracture	Injury, poisoning and procedural complications	21	0.00 %
Altered visual depth perception	Eye disorders	20	0.00 %
Anal abscess	Infections and infestations	20	0.00 %
Anorectal disorder	Gastrointestinal disorders	20	0.00 %
Aortitis	Vascular disorders	20	0.00 %
Application site hypoesthesia	General disorders and administration site conditions	20	0.00 %
Blood fibrinogen decreased	Investigations	20	0.00 %
Blood immunoglobulin A increased	Investigations	20	0.00 %
Brain contusion	Injury, poisoning and procedural complications	20	0.00 %
Breast cancer female	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	20	0.00 %
Breast disorder female	Reproductive system and breast disorders	20	0.00 %
Cerebrospinal fluid leakage	Nervous system disorders	20	0.00 %
Cervicogenic headache	Nervous system disorders	20	0.00 %
Cholinergic syndrome	Nervous system disorders	20	0.00 %
Chondrocalcinosis pyrophosphate	Musculoskeletal and connective tissue disorders	20	0.00 %
Chorioretinitis	Infections and infestations	20	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Colour blindness	Congenital, familial and genetic disorders	20	0.00 %
Complicated appendicitis	Infections and infestations	20	0.00 %
Contraindicated product administered	Injury, poisoning and procedural complications	20	0.00 %
CSF oligoclonal band present	Investigations	20	0.00 %
CSF test abnormal	Investigations	20	0.00 %
Cytopenia	Blood and lymphatic system disorders	20	0.00 %
Dermo-hypodermitis	Infections and infestations	20	0.00 %
Diastolic hypertension	Vascular disorders	20	0.00 %
Electroencephalogram abnormal	Investigations	20	0.00 %
Extraocular muscle disorder	Eye disorders	20	0.00 %
Eyelid myokymia	Eye disorders	20	0.00 %
Foetal malformation	Congenital, familial and genetic disorders	20	0.00 %
Gastrointestinal hypomotility	Gastrointestinal disorders	20	0.00 %
Genital discomfort	Reproductive system and breast disorders	20	0.00 %
Gingival recession	Gastrointestinal disorders	20	0.00 %
Haemangioma of liver	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	20	0.00 %
Haemorrhagic ovarian cyst	Reproductive system and breast disorders	20	0.00 %
Hand fracture	Injury, poisoning and procedural complications	20	0.00 %
Heat oedema	Injury, poisoning and procedural complications	20	0.00 %
Hepatic lesion	Hepatobiliary disorders	20	0.00 %
Hepatic mass	Hepatobiliary disorders	20	0.00 %
Herpes zoster disseminated	Infections and infestations	20	0.00 %
Immunoglobulins increased	Investigations	20	0.00 %
Inappropriate antidiuretic hormone secretion	Endocrine disorders	20	0.00 %
Injection	Surgical and medical procedures	20	0.00 %
Intellectual disability	Nervous system disorders	20	0.00 %
Intranasal paraesthesia	Respiratory, thoracic and mediastinal disorders	20	0.00 %
Jaundice cholestatic	Hepatobiliary disorders	20	0.00 %
Joint contracture	Musculoskeletal and connective tissue disorders	20	0.00 %
Large intestine perforation	Gastrointestinal disorders	20	0.00 %
Left atrial dilatation	Cardiac disorders	20	0.00 %
Lymphocytic infiltration	Blood and lymphatic system disorders	20	0.00 %
Mean cell haemoglobin concentration increased	Investigations	20	0.00 %
Meniscus injury	Injury, poisoning and procedural complications	20	0.00 %
Metastasis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	20	0.00 %
Mitral valve disease	Cardiac disorders	20	0.00 %
Neuroborreliosis	Infections and infestations	20	0.00 %
Neurogenic bladder	Renal and urinary disorders	20	0.00 %
Neurological decompensation	Nervous system disorders	20	0.00 %
Orchitis noninfective	Reproductive system and breast disorders	20	0.00 %
Osteonecrosis	Musculoskeletal and connective tissue disorders	20	0.00 %
Overweight	Metabolism and nutrition disorders	20	0.00 %
Phobia	Psychiatric disorders	20	0.00 %
Placental disorder	Pregnancy, puerperium and perinatal conditions	20	0.00 %
Polymerase chain reaction positive	Investigations	20	0.00 %
Product after taste	Product issues	20	0.00 %
Pulse pressure increased	Investigations	20	0.00 %
Pyoderma gangrenosum	Skin and subcutaneous tissue disorders	20	0.00 %
Quadrantanopia	Nervous system disorders	20	0.00 %
Social avoidant behaviour	Psychiatric disorders	20	0.00 %
Spinal compression fracture	Injury, poisoning and procedural complications	20	0.00 %
Spinal cord infarction	Nervous system disorders	20	0.00 %
Status migrainosus	Nervous system disorders	20	0.00 %
Thrombosis in device	Product issues	20	0.00 %
Tongue haemorrhage	Gastrointestinal disorders	20	0.00 %
Urinary occult blood positive	Investigations	20	0.00 %
Uvulitis	Gastrointestinal disorders	20	0.00 %
Vaccination site granuloma	General disorders and administration site conditions	20	0.00 %
Vascular dementia	Nervous system disorders	20	0.00 %
Adenoidal disorder	Respiratory, thoracic and mediastinal disorders	19	0.00 %
Aerophagia	Gastrointestinal disorders	19	0.00 %
Asthma exercise induced	Respiratory, thoracic and mediastinal disorders	19	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Blood oestrogen decreased	Investigations	19	0.00 %
Blood pH increased	Investigations	19	0.00 %
Bone marrow failure	Blood and lymphatic system disorders	19	0.00 %
Brain hypoxia	Nervous system disorders	19	0.00 %
Burn oesophageal	Injury, poisoning and procedural complications	19	0.00 %
Cerebellar ischaemia	Nervous system disorders	19	0.00 %
Cerebral arteriosclerosis	Nervous system disorders	19	0.00 %
Choluria	Renal and urinary disorders	19	0.00 %
Clostridium difficile colitis	Infections and infestations	19	0.00 %
Conjunctivitis bacterial	Infections and infestations	19	0.00 %
Consciousness fluctuating	Nervous system disorders	19	0.00 %
Cor pulmonale	Cardiac disorders	19	0.00 %
Cubital tunnel syndrome	Nervous system disorders	19	0.00 %
Delirium febrile	Psychiatric disorders	19	0.00 %
Dental caries	Gastrointestinal disorders	19	0.00 %
Dermatitis exfoliative	Skin and subcutaneous tissue disorders	19	0.00 %
Device related infection	Infections and infestations	19	0.00 %
Disease susceptibility	General disorders and administration site conditions	19	0.00 %
Duodenogastric reflux	Gastrointestinal disorders	19	0.00 %
Dysmetria	Nervous system disorders	19	0.00 %
Ear injury	Injury, poisoning and procedural complications	19	0.00 %
Eczema weeping	Skin and subcutaneous tissue disorders	19	0.00 %
Endolymphatic hydrops	Ear and labyrinth disorders	19	0.00 %
Eyelid margin crusting	Eye disorders	19	0.00 %
Feeling of relaxation	General disorders and administration site conditions	19	0.00 %
Gastritis erosive	Gastrointestinal disorders	19	0.00 %
Genital tract inflammation	Reproductive system and breast disorders	19	0.00 %
Gestational diabetes	Pregnancy, puerperium and perinatal conditions	19	0.00 %
Increased viscosity of bronchial secretion	Respiratory, thoracic and mediastinal disorders	19	0.00 %
Indifference	Psychiatric disorders	19	0.00 %
Injection site joint movement impairment	General disorders and administration site conditions	19	0.00 %
Jaw clicking	Musculoskeletal and connective tissue disorders	19	0.00 %
Leiomyoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	19	0.00 %
Loss of proprioception	Nervous system disorders	19	0.00 %
Malabsorption	Gastrointestinal disorders	19	0.00 %
Mastoiditis	Infections and infestations	19	0.00 %
Palindromic rheumatism	Musculoskeletal and connective tissue disorders	19	0.00 %
Pancreatitis necrotising	Gastrointestinal disorders	19	0.00 %
Peripheral nerve paresis	Nervous system disorders	19	0.00 %
Pharyngeal enanthema	Respiratory, thoracic and mediastinal disorders	19	0.00 %
Psychological trauma	Psychiatric disorders	19	0.00 %
Pulmonary tuberculosis	Infections and infestations	19	0.00 %
Pupillary disorder	Eye disorders	19	0.00 %
Red blood cell sedimentation rate abnormal	Investigations	19	0.00 %
Renal tubular necrosis	Renal and urinary disorders	19	0.00 %
Respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	19	0.00 %
Restless arm syndrome	Nervous system disorders	19	0.00 %
SARS-CoV-2 antibody test	Investigations	19	0.00 %
Skin test positive	Investigations	19	0.00 %
Small intestinal obstruction	Gastrointestinal disorders	19	0.00 %
Spinal cord injury	Injury, poisoning and procedural complications	19	0.00 %
Thrombolysis	Surgical and medical procedures	19	0.00 %
Tinea pedis	Infections and infestations	19	0.00 %
Tongue injury	Injury, poisoning and procedural complications	19	0.00 %
Ulcerative keratitis	Eye disorders	19	0.00 %
Urticaria thermal	Skin and subcutaneous tissue disorders	19	0.00 %
Vaccination site atrophy	General disorders and administration site conditions	19	0.00 %
Vaccination site cyst	General disorders and administration site conditions	19	0.00 %
Vasculitis necrotising	Vascular disorders	19	0.00 %
Volvulus	Gastrointestinal disorders	19	0.00 %
Abdominal infection	Infections and infestations	18	0.00 %
Abortion early	Pregnancy, puerperium and perinatal conditions	18	0.00 %
Abulia	Psychiatric disorders	18	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Acute macular neuroretinopathy	Eye disorders	18	0.00 %
Antineutrophil cytoplasmic antibody positive	Investigations	18	0.00 %
Appendix disorder	Gastrointestinal disorders	18	0.00 %
Application site warmth	General disorders and administration site conditions	18	0.00 %
Axillary lymphadenectomy	Surgical and medical procedures	18	0.00 %
B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	18	0.00 %
Bacterial sepsis	Infections and infestations	18	0.00 %
Basal ganglia infarction	Nervous system disorders	18	0.00 %
Blood immunoglobulin M increased	Investigations	18	0.00 %
Blood thyroid stimulating hormone abnormal	Investigations	18	0.00 %
Calculus urinary	Renal and urinary disorders	18	0.00 %
Cerebral ventricle dilatation	Nervous system disorders	18	0.00 %
Chronic pigmented purpura	Skin and subcutaneous tissue disorders	18	0.00 %
Claustrophobia	Psychiatric disorders	18	0.00 %
Clinically isolated syndrome	Nervous system disorders	18	0.00 %
Dactylitis	Musculoskeletal and connective tissue disorders	18	0.00 %
Dermatitis herpetiformis	Skin and subcutaneous tissue disorders	18	0.00 %
Ehlers-Danlos syndrome	Congenital, familial and genetic disorders	18	0.00 %
Ejaculation disorder	Reproductive system and breast disorders	18	0.00 %
Ejaculation failure	Reproductive system and breast disorders	18	0.00 %
Ejection fraction abnormal	Investigations	18	0.00 %
Endometrial disorder	Reproductive system and breast disorders	18	0.00 %
Epiglottic oedema	Respiratory, thoracic and mediastinal disorders	18	0.00 %
Epileptic aura	Nervous system disorders	18	0.00 %
Epinephrine increased	Investigations	18	0.00 %
Epstein-Barr virus test positive	Investigations	18	0.00 %
Escherichia sepsis	Infections and infestations	18	0.00 %
Extremity necrosis	Vascular disorders	18	0.00 %
Febrile infection	Infections and infestations	18	0.00 %
Fibrin D dimer	Investigations	18	0.00 %
Focal dyscognitive seizures	Nervous system disorders	18	0.00 %
Foetal cardiac arrest	Cardiac disorders	18	0.00 %
Gingival ulceration	Gastrointestinal disorders	18	0.00 %
High density lipoprotein increased	Investigations	18	0.00 %
Hypermetabolism	Metabolism and nutrition disorders	18	0.00 %
Hypoaesthesia teeth	Gastrointestinal disorders	18	0.00 %
Infection reactivation	Infections and infestations	18	0.00 %
Injection site indentation	General disorders and administration site conditions	18	0.00 %
Intentional product use issue	Injury, poisoning and procedural complications	18	0.00 %
Liver abscess	Infections and infestations	18	0.00 %
Mean platelet volume increased	Investigations	18	0.00 %
Medical induction of coma	Surgical and medical procedures	18	0.00 %
Meralgia paraesthesia	Nervous system disorders	18	0.00 %
Mouth breathing	Respiratory, thoracic and mediastinal disorders	18	0.00 %
Nasal discharge discolouration	Respiratory, thoracic and mediastinal disorders	18	0.00 %
Nasal vestibulitis	Infections and infestations	18	0.00 %
Nerve conduction studies abnormal	Investigations	18	0.00 %
Nipple inflammation	Reproductive system and breast disorders	18	0.00 %
Oedema genital	Reproductive system and breast disorders	18	0.00 %
Oesophageal discomfort	Gastrointestinal disorders	18	0.00 %
Palmoplantar pustulosis	Skin and subcutaneous tissue disorders	18	0.00 %
Papilloma viral infection	Infections and infestations	18	0.00 %
Peak expiratory flow rate decreased	Investigations	18	0.00 %
Peptic ulcer haemorrhage	Gastrointestinal disorders	18	0.00 %
Perivasicular dermatitis	Skin and subcutaneous tissue disorders	18	0.00 %
Pertussis	Infections and infestations	18	0.00 %
Plicated tongue	Gastrointestinal disorders	18	0.00 %
Post procedural complication	Injury, poisoning and procedural complications	18	0.00 %
Post-traumatic neck syndrome	Injury, poisoning and procedural complications	18	0.00 %
Post-traumatic pain	Injury, poisoning and procedural complications	18	0.00 %
Product expiration date issue	Product issues	18	0.00 %
Prostatomegaly	Reproductive system and breast disorders	18	0.00 %
Protein urine	Investigations	18	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Reaction to preservatives	Immune system disorders	18	0.00 %
Red blood cells urine positive	Investigations	18	0.00 %
Renal haemorrhage	Renal and urinary disorders	18	0.00 %
Renal vein thrombosis	Renal and urinary disorders	18	0.00 %
Retinopathy	Eye disorders	18	0.00 %
Scar inflammation	General disorders and administration site conditions	18	0.00 %
Self-injurious ideation	Psychiatric disorders	18	0.00 %
Skin indentation	Skin and subcutaneous tissue disorders	18	0.00 %
Sleep talking	Psychiatric disorders	18	0.00 %
Small intestinal haemorrhage	Gastrointestinal disorders	18	0.00 %
Splenic rupture	Injury, poisoning and procedural complications	18	0.00 %
Therapeutic product effect incomplete	General disorders and administration site conditions	18	0.00 %
Trigeminal palsy	Nervous system disorders	18	0.00 %
Troponin decreased	Investigations	18	0.00 %
Urinary tract discomfort	Renal and urinary disorders	18	0.00 %
Vascular encephalopathy	Nervous system disorders	18	0.00 %
Visual acuity reduced transiently	Eye disorders	18	0.00 %
Wrong schedule	Injury, poisoning and procedural complications	18	0.00 %
Acute psychosis	Psychiatric disorders	17	0.00 %
Alanine aminotransferase abnormal	Investigations	17	0.00 %
Alveolitis	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Anal fissure	Gastrointestinal disorders	17	0.00 %
Angle closure glaucoma	Eye disorders	17	0.00 %
Anterograde amnesia	Nervous system disorders	17	0.00 %
Arachnoid cyst	Nervous system disorders	17	0.00 %
Arterial rupture	Vascular disorders	17	0.00 %
Autism spectrum disorder	Psychiatric disorders	17	0.00 %
Axonal and demyelinating polyneuropathy	Nervous system disorders	17	0.00 %
Bile duct stone	Hepatobiliary disorders	17	0.00 %
Bilirubin conjugated increased	Investigations	17	0.00 %
Blood sodium increased	Investigations	17	0.00 %
Bronchial obstruction	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Bronchial secretion retention	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Bundle branch block	Cardiac disorders	17	0.00 %
Carcinoembryonic antigen increased	Investigations	17	0.00 %
Cholecystectomy	Surgical and medical procedures	17	0.00 %
Coating in mouth	Gastrointestinal disorders	17	0.00 %
Complication associated with device	General disorders and administration site conditions	17	0.00 %
Cramp-fasciculation syndrome	Nervous system disorders	17	0.00 %
Delusional perception	Psychiatric disorders	17	0.00 %
Device issue	Product issues	17	0.00 %
Dilatation ventricular	Cardiac disorders	17	0.00 %
Disturbance in sexual arousal	Psychiatric disorders	17	0.00 %
Endometrial hyperplasia	Reproductive system and breast disorders	17	0.00 %
Enteritis infectious	Infections and infestations	17	0.00 %
Enterococcal infection	Infections and infestations	17	0.00 %
Eyelid skin dryness	Eye disorders	17	0.00 %
Fear of disease	Psychiatric disorders	17	0.00 %
Fibrin degradation products increased	Investigations	17	0.00 %
Gilbert's syndrome	Congenital, familial and genetic disorders	17	0.00 %
Hemihyperesthesia	Nervous system disorders	17	0.00 %
Hepatic cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17	0.00 %
Hypergammaglobulinaemia	Blood and lymphatic system disorders	17	0.00 %
Hyperlactacidaemia	Metabolism and nutrition disorders	17	0.00 %
Hypertensive encephalopathy	Nervous system disorders	17	0.00 %
Hypophosphataemia	Metabolism and nutrition disorders	17	0.00 %
Impatience	Psychiatric disorders	17	0.00 %
Intrusive thoughts	Psychiatric disorders	17	0.00 %
Irregular sleep wake rhythm disorder	Nervous system disorders	17	0.00 %
Jaw fracture	Injury, poisoning and procedural complications	17	0.00 %
Laryngeal disorder	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Lateral medullary syndrome	Nervous system disorders	17	0.00 %
Lhermitte's sign	Nervous system disorders	17	0.00 %
Logorrhoea	Psychiatric disorders	17	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Lung hyperinflation	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Malignant hypertension	Vascular disorders	17	0.00 %
Malignant melanoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17	0.00 %
Mass excision	Surgical and medical procedures	17	0.00 %
Mixed connective tissue disease	Musculoskeletal and connective tissue disorders	17	0.00 %
Myoclonic epilepsy	Nervous system disorders	17	0.00 %
Necrotising fasciitis	Infections and infestations	17	0.00 %
Obsessive-compulsive disorder	Psychiatric disorders	17	0.00 %
Oculogyric crisis	Eye disorders	17	0.00 %
Organic erectile dysfunction	Reproductive system and breast disorders	17	0.00 %
Oropharyngeal plaque	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Ovarian haemorrhage	Reproductive system and breast disorders	17	0.00 %
Pneumonia klebsiella	Infections and infestations	17	0.00 %
Priapism	Reproductive system and breast disorders	17	0.00 %
Pulmonary sepsis	Infections and infestations	17	0.00 %
Puncture site oedema	General disorders and administration site conditions	17	0.00 %
Pyelitis	Infections and infestations	17	0.00 %
Pyramidal tract syndrome	Nervous system disorders	17	0.00 %
Retinal injury	Injury, poisoning and procedural complications	17	0.00 %
Retinal ischaemia	Eye disorders	17	0.00 %
Rhinovirus infection	Infections and infestations	17	0.00 %
SARS-CoV-2 test false positive	Investigations	17	0.00 %
Skin cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17	0.00 %
Skull fracture	Injury, poisoning and procedural complications	17	0.00 %
Soft tissue disorder	Musculoskeletal and connective tissue disorders	17	0.00 %
Stertor	Respiratory, thoracic and mediastinal disorders	17	0.00 %
Systemic lupus erythematosus rash	Skin and subcutaneous tissue disorders	17	0.00 %
Therapeutic response decreased	General disorders and administration site conditions	17	0.00 %
Thyroxine free increased	Investigations	17	0.00 %
Vaccination site joint warmth	General disorders and administration site conditions	17	0.00 %
Vaccination site ulcer	General disorders and administration site conditions	17	0.00 %
Vaccine associated enhanced disease	Immune system disorders	17	0.00 %
Vertebrobasilar stroke	Nervous system disorders	17	0.00 %
Achenbach syndrome	Vascular disorders	16	0.00 %
Acute lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	16	0.00 %
Adhesion	General disorders and administration site conditions	16	0.00 %
Amniotic cavity infection	Infections and infestations	16	0.00 %
Antisynthetase syndrome	Musculoskeletal and connective tissue disorders	16	0.00 %
Application site lymphadenopathy	General disorders and administration site conditions	16	0.00 %
Arterial haemorrhage	Vascular disorders	16	0.00 %
Beta haemolytic streptococcal infection	Infections and infestations	16	0.00 %
Bladder dilatation	Renal and urinary disorders	16	0.00 %
Blood cholesterol decreased	Investigations	16	0.00 %
Blood pressure ambulatory increased	Investigations	16	0.00 %
Brain compression	Nervous system disorders	16	0.00 %
Capillaritis	Skin and subcutaneous tissue disorders	16	0.00 %
Capillary nail refill test abnormal	Investigations	16	0.00 %
Cerebral amyloid angiopathy	Nervous system disorders	16	0.00 %
Cerebral microhaemorrhage	Nervous system disorders	16	0.00 %
Cervical spinal stenosis	Musculoskeletal and connective tissue disorders	16	0.00 %
Cholecystitis infective	Infections and infestations	16	0.00 %
Computerised tomogram abnormal	Investigations	16	0.00 %
Counterfeit product administered	Injury, poisoning and procedural complications	16	0.00 %
Cystoid macular oedema	Eye disorders	16	0.00 %
Dengue fever	Infections and infestations	16	0.00 %
Dependence on oxygen therapy	Social circumstances	16	0.00 %
Diaphragmatic spasm	Respiratory, thoracic and mediastinal disorders	16	0.00 %
Diffuse large B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	16	0.00 %
Drop attacks	Nervous system disorders	16	0.00 %
Duodenal ulcer	Gastrointestinal disorders	16	0.00 %
Duodenitis	Gastrointestinal disorders	16	0.00 %
Eczema herpeticum	Infections and infestations	16	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Electrocardiogram QRS complex prolonged	Investigations	16	0.00 %
Epiglottitis	Infections and infestations	16	0.00 %
External ear inflammation	Ear and labyrinth disorders	16	0.00 %
Extravasation blood	Vascular disorders	16	0.00 %
Fibroadenoma of breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	16	0.00 %
Fistula	Musculoskeletal and connective tissue disorders	16	0.00 %
Foetal movement disorder	Nervous system disorders	16	0.00 %
Genital blister	Reproductive system and breast disorders	16	0.00 %
Genital erythema	Reproductive system and breast disorders	16	0.00 %
Genital paraesthesia	Reproductive system and breast disorders	16	0.00 %
Glomerulonephritis membranous	Renal and urinary disorders	16	0.00 %
Heart rate variability increased	Investigations	16	0.00 %
Hepatitis E	Infections and infestations	16	0.00 %
Hepatitis toxic	Hepatobiliary disorders	16	0.00 %
Herpes simplex encephalitis	Infections and infestations	16	0.00 %
Histamine level increased	Investigations	16	0.00 %
Hypertrophy	General disorders and administration site conditions	16	0.00 %
Hypertrophy of tongue papillae	Gastrointestinal disorders	16	0.00 %
IIIrd nerve disorder	Nervous system disorders	16	0.00 %
Incorrect product formulation administered	Injury, poisoning and procedural complications	16	0.00 %
Interleukin level increased	Investigations	16	0.00 %
Jaundice neonatal	Pregnancy, puerperium and perinatal conditions	16	0.00 %
Laryngeal stenosis	Respiratory, thoracic and mediastinal disorders	16	0.00 %
Malignant neoplasm progression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	16	0.00 %
Mesenteric panniculitis	Gastrointestinal disorders	16	0.00 %
Metastases to lung	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	16	0.00 %
Mixed liver injury	Hepatobiliary disorders	16	0.00 %
Mouth cyst	Gastrointestinal disorders	16	0.00 %
Multisystem inflammatory syndrome in adults	Immune system disorders	16	0.00 %
Myasthenia gravis crisis	Nervous system disorders	16	0.00 %
Near drowning	Injury, poisoning and procedural complications	16	0.00 %
Nerve block	Surgical and medical procedures	16	0.00 %
Onychomycosis	Infections and infestations	16	0.00 %
Oral allergy syndrome	Immune system disorders	16	0.00 %
Oral mucosal roughening	Gastrointestinal disorders	16	0.00 %
Otitis media chronic	Infections and infestations	16	0.00 %
Ovarian failure	Reproductive system and breast disorders	16	0.00 %
Oxygen saturation	Investigations	16	0.00 %
Pericarditis infective	Infections and infestations	16	0.00 %
Persistent depressive disorder	Psychiatric disorders	16	0.00 %
Plantar erythema	Skin and subcutaneous tissue disorders	16	0.00 %
Portosplenomesenteric venous thrombosis	Hepatobiliary disorders	16	0.00 %
Primary headache associated with sexual activity	Nervous system disorders	16	0.00 %
Product taste abnormal	Product issues	16	0.00 %
Puncture site induration	General disorders and administration site conditions	16	0.00 %
Rectal discharge	Gastrointestinal disorders	16	0.00 %
Red blood cell abnormality	Blood and lymphatic system disorders	16	0.00 %
Relapsing-remitting multiple sclerosis	Nervous system disorders	16	0.00 %
Renal injury	Renal and urinary disorders	16	0.00 %
Respiratory muscle weakness	Respiratory, thoracic and mediastinal disorders	16	0.00 %
Retinal degeneration	Eye disorders	16	0.00 %
Sinus arrest	Cardiac disorders	16	0.00 %
Sputum purulent	Infections and infestations	16	0.00 %
Sticky skin	Skin and subcutaneous tissue disorders	16	0.00 %
Stress urinary incontinence	Renal and urinary disorders	16	0.00 %
Subileus	Gastrointestinal disorders	16	0.00 %
Tendon sheath disorder	Musculoskeletal and connective tissue disorders	16	0.00 %
Testis discomfort	Reproductive system and breast disorders	16	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Thermohypoesthesia	Nervous system disorders	16	0.00 %
Tinea versicolour	Infections and infestations	16	0.00 %
Tracheal inflammation	Respiratory, thoracic and mediastinal disorders	16	0.00 %
Tracheal stenosis	Respiratory, thoracic and mediastinal disorders	16	0.00 %
Trichodynbia	Skin and subcutaneous tissue disorders	16	0.00 %
Vulvovaginal erythema	Reproductive system and breast disorders	16	0.00 %
White blood cells urine	Investigations	16	0.00 %
Albumin globulin ratio decreased	Investigations	15	0.00 %
Androgenetic alopecia	Skin and subcutaneous tissue disorders	15	0.00 %
Anogenital warts	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	0.00 %
Autoimmune pancreatitis	Gastrointestinal disorders	15	0.00 %
Biliary dilatation	Hepatobiliary disorders	15	0.00 %
Bladder sphincter atony	Renal and urinary disorders	15	0.00 %
Blood creatinine abnormal	Investigations	15	0.00 %
Borrelia test positive	Investigations	15	0.00 %
Cartilage injury	Injury, poisoning and procedural complications	15	0.00 %
Cataplexy	Nervous system disorders	15	0.00 %
Cauda equina syndrome	Nervous system disorders	15	0.00 %
Cerebral palsy	Congenital, familial and genetic disorders	15	0.00 %
Cerebral ventricular rupture	Nervous system disorders	15	0.00 %
Chronic respiratory failure	Respiratory, thoracic and mediastinal disorders	15	0.00 %
Cortisol decreased	Investigations	15	0.00 %
Cortisol increased	Investigations	15	0.00 %
Encephalitis brain stem	Infections and infestations	15	0.00 %
Erythema migrans	Infections and infestations	15	0.00 %
Escherichia test positive	Investigations	15	0.00 %
Essential thrombocythaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	0.00 %
Exercise lack of	Social circumstances	15	0.00 %
Eye ulcer	Eye disorders	15	0.00 %
Eyelid cyst	Eye disorders	15	0.00 %
Factor V Leiden mutation	Congenital, familial and genetic disorders	15	0.00 %
Fat tissue increased	General disorders and administration site conditions	15	0.00 %
Focal segmental glomerulosclerosis	Renal and urinary disorders	15	0.00 %
Foreign body in eye	Injury, poisoning and procedural complications	15	0.00 %
Gastrointestinal wall thickening	Gastrointestinal disorders	15	0.00 %
Herpes simplex test positive	Investigations	15	0.00 %
Hospitalisation	Surgical and medical procedures	15	0.00 %
Hydrothorax	Respiratory, thoracic and mediastinal disorders	15	0.00 %
Hypoproteinaemia	Metabolism and nutrition disorders	15	0.00 %
Hypotrichosis	Skin and subcutaneous tissue disorders	15	0.00 %
Implant site pain	General disorders and administration site conditions	15	0.00 %
Implant site swelling	General disorders and administration site conditions	15	0.00 %
Infrequent bowel movements	Gastrointestinal disorders	15	0.00 %
Injection site discolouration	General disorders and administration site conditions	15	0.00 %
Intraocular pressure test abnormal	Investigations	15	0.00 %
Keratosis pilaris	Skin and subcutaneous tissue disorders	15	0.00 %
Lithiasis	General disorders and administration site conditions	15	0.00 %
Loefgren syndrome	Immune system disorders	15	0.00 %
Lumbar radiculopathy	Nervous system disorders	15	0.00 %
Lumbar vertebral fracture	Injury, poisoning and procedural complications	15	0.00 %
Myelosuppression	Blood and lymphatic system disorders	15	0.00 %
Occupational exposure to SARS-CoV-2	Injury, poisoning and procedural complications	15	0.00 %
Oesophageal disorder	Gastrointestinal disorders	15	0.00 %
Ovarian vein thrombosis	Reproductive system and breast disorders	15	0.00 %
Paresis cranial nerve	Nervous system disorders	15	0.00 %
PCO2 increased	Investigations	15	0.00 %
Periorbital discomfort	Eye disorders	15	0.00 %
Peripheral nerve injury	Injury, poisoning and procedural complications	15	0.00 %
Pneumomediastinum	Respiratory, thoracic and mediastinal disorders	15	0.00 %
Polymenorrhagia	Reproductive system and breast disorders	15	0.00 %
Postictal paralysis	Nervous system disorders	15	0.00 %
Prerenal failure	Renal and urinary disorders	15	0.00 %
Primary biliary cholangitis	Hepatobiliary disorders	15	0.00 %
Product use in unapproved indication	Injury, poisoning and procedural complications	15	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Pseudomonas infection	Infections and infestations	15	0.00 %
Pubic pain	Musculoskeletal and connective tissue disorders	15	0.00 %
Pudendal canal syndrome	Nervous system disorders	15	0.00 %
Radicular pain	Nervous system disorders	15	0.00 %
Relapsing fever	Infections and infestations	15	0.00 %
Renal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	0.00 %
Salivary gland disorder	Gastrointestinal disorders	15	0.00 %
Spontaneous penile erection	Reproductive system and breast disorders	15	0.00 %
Squamous cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	0.00 %
Stress at work	Social circumstances	15	0.00 %
Surgery	Surgical and medical procedures	15	0.00 %
Syphilis	Infections and infestations	15	0.00 %
Throat lesion	Respiratory, thoracic and mediastinal disorders	15	0.00 %
Ulnar neuritis	Nervous system disorders	15	0.00 %
Urticaria cholinergic	Skin and subcutaneous tissue disorders	15	0.00 %
Uterine dilation and curettage	Surgical and medical procedures	15	0.00 %
Vaccination site thrombosis	General disorders and administration site conditions	15	0.00 %
Vascular stent thrombosis	General disorders and administration site conditions	15	0.00 %
Winged scapula	Musculoskeletal and connective tissue disorders	15	0.00 %
Wolff-Parkinson-White syndrome	Cardiac disorders	15	0.00 %
Acoustic neuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	14	0.00 %
Alcohol interaction	General disorders and administration site conditions	14	0.00 %
Allergic sinusitis	Respiratory, thoracic and mediastinal disorders	14	0.00 %
Anhidrosis	Skin and subcutaneous tissue disorders	14	0.00 %
Aspartate aminotransferase abnormal	Investigations	14	0.00 %
Autoimmune neuropathy	Nervous system disorders	14	0.00 %
Blister rupture	Skin and subcutaneous tissue disorders	14	0.00 %
Blood alkaline phosphatase decreased	Investigations	14	0.00 %
Blood phosphorus increased	Investigations	14	0.00 %
Blood testosterone decreased	Investigations	14	0.00 %
Bone marrow disorder	Blood and lymphatic system disorders	14	0.00 %
Brachial plexus injury	Injury, poisoning and procedural complications	14	0.00 %
Bradyarrhythmia	Cardiac disorders	14	0.00 %
Bronchitis bacterial	Infections and infestations	14	0.00 %
Croup infectious	Infections and infestations	14	0.00 %
Crystal arthropathy	Musculoskeletal and connective tissue disorders	14	0.00 %
Cyst rupture	General disorders and administration site conditions	14	0.00 %
Drainage	Surgical and medical procedures	14	0.00 %
Dreamy state	Nervous system disorders	14	0.00 %
Dupuytren's contracture	Musculoskeletal and connective tissue disorders	14	0.00 %
Dysbiosis	Gastrointestinal disorders	14	0.00 %
End stage renal disease	Renal and urinary disorders	14	0.00 %
Erythrodermic psoriasis	Skin and subcutaneous tissue disorders	14	0.00 %
Gallbladder enlargement	Hepatobiliary disorders	14	0.00 %
Gastric antral vascular ectasia	Gastrointestinal disorders	14	0.00 %
Gastric ulcer haemorrhage	Gastrointestinal disorders	14	0.00 %
Gingival abscess	Infections and infestations	14	0.00 %
Glomerular filtration rate increased	Investigations	14	0.00 %
Hemiataxia	Nervous system disorders	14	0.00 %
Histiocytic necrotising lymphadenitis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	14	0.00 %
Hypovolaemia	Metabolism and nutrition disorders	14	0.00 %
Inguinal mass	Musculoskeletal and connective tissue disorders	14	0.00 %
Large intestine infection	Infections and infestations	14	0.00 %
Libido disorder	Psychiatric disorders	14	0.00 %
Lumbar spinal stenosis	Musculoskeletal and connective tissue disorders	14	0.00 %
Lymphocyte count abnormal	Investigations	14	0.00 %
Macular hole	Eye disorders	14	0.00 %
Mean platelet volume decreased	Investigations	14	0.00 %
Meningoradiculitis	Nervous system disorders	14	0.00 %
Monocyte percentage increased	Investigations	14	0.00 %
Morphea	Musculoskeletal and connective tissue disorders	14	0.00 %
Neurological examination abnormal	Investigations	14	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Normochromic normocytic anaemia	Blood and lymphatic system disorders	14	0.00 %
Nothing by mouth order	Surgical and medical procedures	14	0.00 %
Oligohydramnios	Pregnancy, puerperium and perinatal conditions	14	0.00 %
Oral contusion	Injury, poisoning and procedural complications	14	0.00 %
Pancreatic enzymes increased	Investigations	14	0.00 %
Pericarditis constrictive	Cardiac disorders	14	0.00 %
Phobic postural vertigo	Ear and labyrinth disorders	14	0.00 %
Pityriasis lichenoides et varioliformis acuta	Skin and subcutaneous tissue disorders	14	0.00 %
Pleural thickening	Respiratory, thoracic and mediastinal disorders	14	0.00 %
Polymorphic light eruption	Skin and subcutaneous tissue disorders	14	0.00 %
Post thrombotic syndrome	Vascular disorders	14	0.00 %
Pregnancy on oral contraceptive	Pregnancy, puerperium and perinatal conditions	14	0.00 %
Procedural nausea	Injury, poisoning and procedural complications	14	0.00 %
Product contamination	Product issues	14	0.00 %
Product lot number issue	Product issues	14	0.00 %
Purpura non-thrombocytopenic	Blood and lymphatic system disorders	14	0.00 %
Renal artery thrombosis	Renal and urinary disorders	14	0.00 %
Retinal artery embolism	Eye disorders	14	0.00 %
Romberg test positive	Investigations	14	0.00 %
Serositis	General disorders and administration site conditions	14	0.00 %
Skin bacterial infection	Infections and infestations	14	0.00 %
Specialist consultation	Surgical and medical procedures	14	0.00 %
Staphylococcal sepsis	Infections and infestations	14	0.00 %
Streptococcus test positive	Investigations	14	0.00 %
Tardive dyskinesia	Nervous system disorders	14	0.00 %
Terminal state	General disorders and administration site conditions	14	0.00 %
Threatened labour	Pregnancy, puerperium and perinatal conditions	14	0.00 %
Time perception altered	Psychiatric disorders	14	0.00 %
Tooth discolouration	Gastrointestinal disorders	14	0.00 %
Toxoplasmosis	Infections and infestations	14	0.00 %
Urge incontinence	Renal and urinary disorders	14	0.00 %
Ventricular septal defect	Congenital, familial and genetic disorders	14	0.00 %
Vogt-Koyanagi-Harada disease	Eye disorders	14	0.00 %
Abnormal clotting factor	Blood and lymphatic system disorders	13	0.00 %
Acute cardiac event	Cardiac disorders	13	0.00 %
Acute motor axonal neuropathy	Nervous system disorders	13	0.00 %
Administration site movement impairment	General disorders and administration site conditions	13	0.00 %
Adverse food reaction	General disorders and administration site conditions	13	0.00 %
Age-related macular degeneration	Eye disorders	13	0.00 %
Alcoholism	Psychiatric disorders	13	0.00 %
Antinuclear antibody	Investigations	13	0.00 %
Asterixis	Nervous system disorders	13	0.00 %
Aversion	Psychiatric disorders	13	0.00 %
Binocular eye movement disorder	Eye disorders	13	0.00 %
Blood albumin increased	Investigations	13	0.00 %
Blood cholesterol abnormal	Investigations	13	0.00 %
Blood lactic acid	Investigations	13	0.00 %
Breast cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13	0.00 %
Bursal fluid accumulation	Musculoskeletal and connective tissue disorders	13	0.00 %
Carbohydrate antigen 125 increased	Investigations	13	0.00 %
Cardiac asthma	Cardiac disorders	13	0.00 %
Cardiac pacemaker insertion	Surgical and medical procedures	13	0.00 %
Catatonia	Psychiatric disorders	13	0.00 %
Cerebral congestion	Nervous system disorders	13	0.00 %
Corneal opacity	Eye disorders	13	0.00 %
Cryoglobulinaemia	Vascular disorders	13	0.00 %
Cutaneous sarcoidosis	Skin and subcutaneous tissue disorders	13	0.00 %
Diet refusal	Metabolism and nutrition disorders	13	0.00 %
Dilatation atrial	Cardiac disorders	13	0.00 %
Emotional poverty	Psychiatric disorders	13	0.00 %
Eosinophilic oesophagitis	Gastrointestinal disorders	13	0.00 %
Escherichia bacteraemia	Infections and infestations	13	0.00 %
Eustachian tube disorder	Ear and labyrinth disorders	13	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Eyelid thickening	Eye disorders	13	0.00 %
Fat necrosis	General disorders and administration site conditions	13	0.00 %
Fibrocystic breast disease	Reproductive system and breast disorders	13	0.00 %
Gait deviation	General disorders and administration site conditions	13	0.00 %
Gingival discolouration	Gastrointestinal disorders	13	0.00 %
Haemoperitoneum	Gastrointestinal disorders	13	0.00 %
Heart alteration	Cardiac disorders	13	0.00 %
HELLP syndrome	Pregnancy, puerperium and perinatal conditions	13	0.00 %
Heparin-induced thrombocytopenia	Blood and lymphatic system disorders	13	0.00 %
Hepatic infarction	Hepatobiliary disorders	13	0.00 %
Hepatitis C	Infections and infestations	13	0.00 %
Hepatitis viral	Infections and infestations	13	0.00 %
Housebound	Social circumstances	13	0.00 %
Hypohidrosis	Skin and subcutaneous tissue disorders	13	0.00 %
Hypomagnesaemia	Metabolism and nutrition disorders	13	0.00 %
Infected bite	Infections and infestations	13	0.00 %
Intra-abdominal fluid collection	Gastrointestinal disorders	13	0.00 %
Invasive ductal breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13	0.00 %
Knee arthroplasty	Surgical and medical procedures	13	0.00 %
Lacrimation decreased	Eye disorders	13	0.00 %
Large intestine polyp	Gastrointestinal disorders	13	0.00 %
Lichen planopilaris	Skin and subcutaneous tissue disorders	13	0.00 %
Ligament injury	Injury, poisoning and procedural complications	13	0.00 %
Lumbosacral radiculopathy	Nervous system disorders	13	0.00 %
Lupus nephritis	Renal and urinary disorders	13	0.00 %
Lymphostasis	Vascular disorders	13	0.00 %
Medial tibial stress syndrome	Musculoskeletal and connective tissue disorders	13	0.00 %
Metastases to central nervous system	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13	0.00 %
Multiple fractures	Injury, poisoning and procedural complications	13	0.00 %
Needle track marks	Skin and subcutaneous tissue disorders	13	0.00 %
Neonatal insufficient breast milk syndrome	Metabolism and nutrition disorders	13	0.00 %
Neonatal respiratory distress	Respiratory, thoracic and mediastinal disorders	13	0.00 %
Nodular rash	Skin and subcutaneous tissue disorders	13	0.00 %
Omental infarction	Gastrointestinal disorders	13	0.00 %
Oral contraception	Surgical and medical procedures	13	0.00 %
Orbital swelling	Eye disorders	13	0.00 %
Ovarian cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13	0.00 %
Ovarian enlargement	Reproductive system and breast disorders	13	0.00 %
Pancreatic cyst	Gastrointestinal disorders	13	0.00 %
Patient elopement	Nervous system disorders	13	0.00 %
PCO2 decreased	Investigations	13	0.00 %
Penile oedema	Reproductive system and breast disorders	13	0.00 %
Perineal pain	Reproductive system and breast disorders	13	0.00 %
Peripheral nerve palsy	Nervous system disorders	13	0.00 %
Piriformis syndrome	Nervous system disorders	13	0.00 %
Pneumocystis jirovecii pneumonia	Infections and infestations	13	0.00 %
Polyarteritis nodosa	Vascular disorders	13	0.00 %
Polymers allergy	Immune system disorders	13	0.00 %
Poor milk ejection reflex	Reproductive system and breast disorders	13	0.00 %
Poor venous access	Vascular disorders	13	0.00 %
Post lumbar puncture syndrome	Injury, poisoning and procedural complications	13	0.00 %
Post procedural haemorrhage	Injury, poisoning and procedural complications	13	0.00 %
Procedural dizziness	Injury, poisoning and procedural complications	13	0.00 %
Product prescribing error	Injury, poisoning and procedural complications	13	0.00 %
Prostatic disorder	Reproductive system and breast disorders	13	0.00 %
Rash rubelliform	Skin and subcutaneous tissue disorders	13	0.00 %
Red cell distribution width decreased	Investigations	13	0.00 %
Retinal vasculitis	Eye disorders	13	0.00 %
Retroplacental haematoma	Pregnancy, puerperium and perinatal conditions	13	0.00 %
Reversible cerebral vasoconstriction syndrome	Nervous system disorders	13	0.00 %
Rheumatic fever	Musculoskeletal and connective tissue disorders	13	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Scleral discolouration	Eye disorders	13	0.00 %
Skeletal injury	Injury, poisoning and procedural complications	13	0.00 %
Soliloquy	Psychiatric disorders	13	0.00 %
Speech disorder developmental	Nervous system disorders	13	0.00 %
Thrombosed varicose vein	Vascular disorders	13	0.00 %
Tongue haematoma	Gastrointestinal disorders	13	0.00 %
Traumatic lung injury	Injury, poisoning and procedural complications	13	0.00 %
Uterine enlargement	Reproductive system and breast disorders	13	0.00 %
Vaccination site anaesthesia	General disorders and administration site conditions	13	0.00 %
Varicocele	Reproductive system and breast disorders	13	0.00 %
Vein collapse	Vascular disorders	13	0.00 %
Visceral pain	General disorders and administration site conditions	13	0.00 %
VIIth nerve disorder	Nervous system disorders	13	0.00 %
Vocal cord dysfunction	Respiratory, thoracic and mediastinal disorders	13	0.00 %
Vocal cord inflammation	Respiratory, thoracic and mediastinal disorders	13	0.00 %
Weight abnormal	Investigations	13	0.00 %
Wrong dose	Injury, poisoning and procedural complications	13	0.00 %
Abdominal hernia	Gastrointestinal disorders	12	0.00 %
Administration site swelling	General disorders and administration site conditions	12	0.00 %
Amylase decreased	Investigations	12	0.00 %
Anaemia vitamin B12 deficiency	Blood and lymphatic system disorders	12	0.00 %
Anamnestic reaction	Immune system disorders	12	0.00 %
Anion gap increased	Investigations	12	0.00 %
Apallic syndrome	Nervous system disorders	12	0.00 %
Autoimmune thyroid disorder	Endocrine disorders	12	0.00 %
Autoinflammatory disease	Immune system disorders	12	0.00 %
Axillary web syndrome	Injury, poisoning and procedural complications	12	0.00 %
Basilar artery occlusion	Nervous system disorders	12	0.00 %
Benign breast neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Bladder cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Blood creatine phosphokinase abnormal	Investigations	12	0.00 %
Blood viscosity increased	Investigations	12	0.00 %
Brain stem ischaemia	Nervous system disorders	12	0.00 %
Campylobacter infection	Infections and infestations	12	0.00 %
Cardiac output decreased	Investigations	12	0.00 %
Cardiolipin antibody positive	Investigations	12	0.00 %
Castleman's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Central vision loss	Eye disorders	12	0.00 %
Cervix haemorrhage uterine	Reproductive system and breast disorders	12	0.00 %
Chondropathy	Musculoskeletal and connective tissue disorders	12	0.00 %
Chronic myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Coagulation test abnormal	Investigations	12	0.00 %
Conjunctival disorder	Eye disorders	12	0.00 %
Conjunctivitis viral	Infections and infestations	12	0.00 %
Cystitis-like symptom	Renal and urinary disorders	12	0.00 %
Dependence on respirator	Respiratory, thoracic and mediastinal disorders	12	0.00 %
Diverticulum intestinal haemorrhagic	Gastrointestinal disorders	12	0.00 %
Duodenal ulcer haemorrhage	Gastrointestinal disorders	12	0.00 %
Endometritis	Infections and infestations	12	0.00 %
Eosinophilic cellulitis	Skin and subcutaneous tissue disorders	12	0.00 %
Foetal distress syndrome	Pregnancy, puerperium and perinatal conditions	12	0.00 %
Full blood count decreased	Investigations	12	0.00 %
Gastric infection	Infections and infestations	12	0.00 %
Gingivitis ulcerative	Gastrointestinal disorders	12	0.00 %
Glucose urine present	Investigations	12	0.00 %
Hand-foot-and-mouth disease	Infections and infestations	12	0.00 %
Hepatitis B	Infections and infestations	12	0.00 %
Hernia pain	General disorders and administration site conditions	12	0.00 %
Hyperhomocysteinaemia	Metabolism and nutrition disorders	12	0.00 %
Immobilisation syndrome	Musculoskeletal and connective tissue disorders	12	0.00 %
Impaired reasoning	Psychiatric disorders	12	0.00 %
Infected cyst	Infections and infestations	12	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Infectious pleural effusion	Infections and infestations	12	0.00 %
Inflammation of wound	Injury, poisoning and procedural complications	12	0.00 %
Inspiratory capacity decreased	Investigations	12	0.00 %
Intra-abdominal haematoma	Gastrointestinal disorders	12	0.00 %
Investigation abnormal	Investigations	12	0.00 %
Ligament disorder	Musculoskeletal and connective tissue disorders	12	0.00 %
Lung cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Lymphocele	Vascular disorders	12	0.00 %
Mastitis postpartum	Infections and infestations	12	0.00 %
Metastases to bone	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Metastatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Milk allergy	Immune system disorders	12	0.00 %
Nasal polyps	Respiratory, thoracic and mediastinal disorders	12	0.00 %
Neurosis	Psychiatric disorders	12	0.00 %
Night blindness	Eye disorders	12	0.00 %
Nodal osteoarthritis	Musculoskeletal and connective tissue disorders	12	0.00 %
Normochromic anaemia	Blood and lymphatic system disorders	12	0.00 %
Occult blood positive	Investigations	12	0.00 %
Ophthalmic artery thrombosis	Eye disorders	12	0.00 %
Oral pustule	Infections and infestations	12	0.00 %
Pancreatitis chronic	Gastrointestinal disorders	12	0.00 %
Paratracheal lymphadenopathy	Blood and lymphatic system disorders	12	0.00 %
Paroxysmal arrhythmia	Cardiac disorders	12	0.00 %
Perichondritis	Infections and infestations	12	0.00 %
Pharyngeal abscess	Infections and infestations	12	0.00 %
Phlebitis deep	Vascular disorders	12	0.00 %
Pituitary tumour benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12	0.00 %
Pityriasis rubra pilaris	Skin and subcutaneous tissue disorders	12	0.00 %
Pneumonia staphylococcal	Infections and infestations	12	0.00 %
Posterior reversible encephalopathy syndrome	Nervous system disorders	12	0.00 %
Progesterone decreased	Investigations	12	0.00 %
Pulmonary microemboli	Respiratory, thoracic and mediastinal disorders	12	0.00 %
Radial nerve injury	Injury, poisoning and procedural complications	12	0.00 %
Red blood cell sedimentation rate decreased	Investigations	12	0.00 %
Respiratory syncytial virus infection	Infections and infestations	12	0.00 %
Retinal vascular disorder	Eye disorders	12	0.00 %
Sensory processing disorder	Nervous system disorders	12	0.00 %
Serum sickness-like reaction	Immune system disorders	12	0.00 %
Skin hypopigmentation	Skin and subcutaneous tissue disorders	12	0.00 %
Soft tissue inflammation	General disorders and administration site conditions	12	0.00 %
Solar lentigo	Skin and subcutaneous tissue disorders	12	0.00 %
Speech sound disorder	Psychiatric disorders	12	0.00 %
Spinal cord compression	Nervous system disorders	12	0.00 %
Strangury	Renal and urinary disorders	12	0.00 %
Systemic scleroderma	Musculoskeletal and connective tissue disorders	12	0.00 %
Tachycardia foetal	Cardiac disorders	12	0.00 %
Temperature perception test increased	Investigations	12	0.00 %
Tenosynovitis stenosans	Musculoskeletal and connective tissue disorders	12	0.00 %
Terminal ileitis	Gastrointestinal disorders	12	0.00 %
Tonsillolith	Respiratory, thoracic and mediastinal disorders	12	0.00 %
Tri-iodothyronine decreased	Investigations	12	0.00 %
Trisomy 21	Congenital, familial and genetic disorders	12	0.00 %
Ulcer haemorrhage	General disorders and administration site conditions	12	0.00 %
Urethritis	Infections and infestations	12	0.00 %
Uterine cyst	Reproductive system and breast disorders	12	0.00 %
Venous haemorrhage	Vascular disorders	12	0.00 %
Venous injury	Injury, poisoning and procedural complications	12	0.00 %
Vertebral artery thrombosis	Nervous system disorders	12	0.00 %
Viral upper respiratory tract infection	Infections and infestations	12	0.00 %
Visceral venous thrombosis	Gastrointestinal disorders	12	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Acute left ventricular failure	Cardiac disorders	11	0.00 %
Agnosia	Nervous system disorders	11	0.00 %
Alanine aminotransferase decreased	Investigations	11	0.00 %
Albuminuria	Renal and urinary disorders	11	0.00 %
Alcohol poisoning	Injury, poisoning and procedural complications	11	0.00 %
Anti-cyclic citrullinated peptide antibody positive	Investigations	11	0.00 %
Antibody test positive	Investigations	11	0.00 %
Antineutrophil cytoplasmic antibody increased	Investigations	11	0.00 %
Aortic disorder	Vascular disorders	11	0.00 %
B-lymphocyte count decreased	Investigations	11	0.00 %
Benign hydatidiform mole	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11	0.00 %
Bickerstaff's encephalitis	Nervous system disorders	11	0.00 %
Bipolar I disorder	Psychiatric disorders	11	0.00 %
Blood homocysteine increased	Investigations	11	0.00 %
Body tinea	Infections and infestations	11	0.00 %
Bradypnoea	Respiratory, thoracic and mediastinal disorders	11	0.00 %
Brain abscess	Infections and infestations	11	0.00 %
Breast atrophy	Reproductive system and breast disorders	11	0.00 %
Breast haemorrhage	Reproductive system and breast disorders	11	0.00 %
Breast neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11	0.00 %
Bronchial wall thickening	Respiratory, thoracic and mediastinal disorders	11	0.00 %
Brugada syndrome	Cardiac disorders	11	0.00 %
Bullous haemorrhagic dermatosis	Skin and subcutaneous tissue disorders	11	0.00 %
C-reactive protein	Investigations	11	0.00 %
Caesarean section	Surgical and medical procedures	11	0.00 %
Calcinosis	General disorders and administration site conditions	11	0.00 %
Campylobacter gastroenteritis	Infections and infestations	11	0.00 %
Carbon dioxide decreased	Investigations	11	0.00 %
Cardiac operation	Surgical and medical procedures	11	0.00 %
Carotid artery disease	Nervous system disorders	11	0.00 %
Cerebral microangiopathy	Nervous system disorders	11	0.00 %
Cervical dysplasia	Reproductive system and breast disorders	11	0.00 %
Cholestatic liver injury	Hepatobiliary disorders	11	0.00 %
Corneal erosion	Eye disorders	11	0.00 %
Coronavirus test positive	Investigations	11	0.00 %
CSF glucose increased	Investigations	11	0.00 %
Cyanopsia	Eye disorders	11	0.00 %
Dairy intolerance	Metabolism and nutrition disorders	11	0.00 %
Defect conduction intraventricular	Cardiac disorders	11	0.00 %
Dermatitis diaper	Skin and subcutaneous tissue disorders	11	0.00 %
Diffuse vasculitis	Vascular disorders	11	0.00 %
Drug level decreased	Investigations	11	0.00 %
Ear canal erythema	Ear and labyrinth disorders	11	0.00 %
Electrocardiogram PR shortened	Investigations	11	0.00 %
Endometrial cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11	0.00 %
Epstein-Barr viraemia	Infections and infestations	11	0.00 %
Exploding head syndrome	Psychiatric disorders	11	0.00 %
Extravasation	General disorders and administration site conditions	11	0.00 %
Faecal volume increased	Investigations	11	0.00 %
Fasting	Social circumstances	11	0.00 %
Genital lesion	Reproductive system and breast disorders	11	0.00 %
Glomerulonephritis acute	Renal and urinary disorders	11	0.00 %
Haemothorax	Respiratory, thoracic and mediastinal disorders	11	0.00 %
Heart rate variability decreased	Investigations	11	0.00 %
Hepatic encephalopathy	Nervous system disorders	11	0.00 %
Hepatic vein thrombosis	Hepatobiliary disorders	11	0.00 %
Hereditary angioedema	Congenital, familial and genetic disorders	11	0.00 %
Hydrocele	Congenital, familial and genetic disorders	11	0.00 %
Hyperlipasaemia	Metabolism and nutrition disorders	11	0.00 %
Hypobarism	Injury, poisoning and procedural complications	11	0.00 %
Hypocapnia	Respiratory, thoracic and mediastinal disorders	11	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Hypopituitarism	Endocrine disorders	11	0.00 %
Hypothalamo-pituitary disorder	Endocrine disorders	11	0.00 %
Infusion site pain	General disorders and administration site conditions	11	0.00 %
Injection site infection	Infections and infestations	11	0.00 %
Ischaemic hepatitis	Hepatobiliary disorders	11	0.00 %
Joint vibration	Musculoskeletal and connective tissue disorders	11	0.00 %
Judgement impaired	Nervous system disorders	11	0.00 %
Kidney enlargement	Renal and urinary disorders	11	0.00 %
Lacrimal disorder	Eye disorders	11	0.00 %
Lacrimation disorder	Eye disorders	11	0.00 %
Large intestinal haemorrhage	Gastrointestinal disorders	11	0.00 %
Lipids abnormal	Investigations	11	0.00 %
Lipids increased	Investigations	11	0.00 %
Local anaesthesia	Surgical and medical procedures	11	0.00 %
Mammogram abnormal	Investigations	11	0.00 %
Mastocytosis	Blood and lymphatic system disorders	11	0.00 %
Misophonia	Ear and labyrinth disorders	11	0.00 %
Monoclonal gammopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11	0.00 %
Neck deformity	Musculoskeletal and connective tissue disorders	11	0.00 %
Necrotic lymphadenopathy	Blood and lymphatic system disorders	11	0.00 %
Non-pitting oedema	General disorders and administration site conditions	11	0.00 %
Oedematous pancreatitis	Gastrointestinal disorders	11	0.00 %
Oesophageal achalasia	Gastrointestinal disorders	11	0.00 %
Optic nerve infarction	Eye disorders	11	0.00 %
Orbital oedema	Eye disorders	11	0.00 %
Orthostatic hypertension	Vascular disorders	11	0.00 %
Oxygen saturation increased	Investigations	11	0.00 %
Pachymeningitis	Nervous system disorders	11	0.00 %
Palpable purpura	Skin and subcutaneous tissue disorders	11	0.00 %
Pancreatic failure	Gastrointestinal disorders	11	0.00 %
Paralysis recurrent laryngeal nerve	Nervous system disorders	11	0.00 %
Partial seizures with secondary generalisation	Nervous system disorders	11	0.00 %
Pelvic girdle pain	Pregnancy, puerperium and perinatal conditions	11	0.00 %
Penile haemorrhage	Reproductive system and breast disorders	11	0.00 %
Perfume sensitivity	Immune system disorders	11	0.00 %
Periostitis	Musculoskeletal and connective tissue disorders	11	0.00 %
Post procedural infection	Infections and infestations	11	0.00 %
Pregnancy with contraceptive device	Pregnancy, puerperium and perinatal conditions	11	0.00 %
Proctitis ulcerative	Gastrointestinal disorders	11	0.00 %
Prolapse	General disorders and administration site conditions	11	0.00 %
Psychotic symptom	Psychiatric disorders	11	0.00 %
Punctate keratitis	Eye disorders	11	0.00 %
Puncture site erythema	General disorders and administration site conditions	11	0.00 %
Radius fracture	Injury, poisoning and procedural complications	11	0.00 %
Rash scarlatiniform	Skin and subcutaneous tissue disorders	11	0.00 %
Recall phenomenon	Injury, poisoning and procedural complications	11	0.00 %
Respiratory tract haemorrhage	Respiratory, thoracic and mediastinal disorders	11	0.00 %
Respiratory tract infection viral	Infections and infestations	11	0.00 %
Retinal infarction	Eye disorders	11	0.00 %
Retroperitoneal haematoma	Gastrointestinal disorders	11	0.00 %
Right ventricular hypertrophy	Cardiac disorders	11	0.00 %
Sacroiliac joint dysfunction	Musculoskeletal and connective tissue disorders	11	0.00 %
Scar discomfort	Skin and subcutaneous tissue disorders	11	0.00 %
Sciatic nerve injury	Injury, poisoning and procedural complications	11	0.00 %
Skull fractured base	Injury, poisoning and procedural complications	11	0.00 %
Spinal column injury	Injury, poisoning and procedural complications	11	0.00 %
Spinal cord ischaemia	Nervous system disorders	11	0.00 %
Spinal deformity	Musculoskeletal and connective tissue disorders	11	0.00 %
Steatorrhoea	Gastrointestinal disorders	11	0.00 %
Streptococcal sepsis	Infections and infestations	11	0.00 %
Suicidal behaviour	Psychiatric disorders	11	0.00 %
Suprapubic pain	General disorders and administration site conditions	11	0.00 %
Symmetrical drug-related intertriginous and flexural exanthema	Skin and subcutaneous tissue disorders	11	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Synovial rupture	Injury, poisoning and procedural complications	11	0.00 %
Tendon calcification	Musculoskeletal and connective tissue disorders	11	0.00 %
Thoracic vertebral fracture	Injury, poisoning and procedural complications	11	0.00 %
Thrombosis mesenteric vessel	Gastrointestinal disorders	11	0.00 %
Thyroxine free decreased	Investigations	11	0.00 %
Tibia fracture	Injury, poisoning and procedural complications	11	0.00 %
Torsade de pointes	Cardiac disorders	11	0.00 %
Traumatic intracranial haemorrhage	Injury, poisoning and procedural complications	11	0.00 %
Ulnar nerve palsy	Nervous system disorders	11	0.00 %
Underweight	Metabolism and nutrition disorders	11	0.00 %
Urine output	Investigations	11	0.00 %
Vaccination site exfoliation	General disorders and administration site conditions	11	0.00 %
Vaginal disorder	Reproductive system and breast disorders	11	0.00 %
Vertebral artery occlusion	Nervous system disorders	11	0.00 %
Viral labyrinthitis	Infections and infestations	11	0.00 %
VIIth nerve paresis	Nervous system disorders	11	0.00 %
Vulval disorder	Reproductive system and breast disorders	11	0.00 %
Vulvitis	Infections and infestations	11	0.00 %
Vulvovaginal injury	Injury, poisoning and procedural complications	11	0.00 %
Xerosis	General disorders and administration site conditions	11	0.00 %
Abdominal abscess	Infections and infestations	10	0.00 %
Abdominal wall haematoma	Gastrointestinal disorders	10	0.00 %
Acetonaemic vomiting	Gastrointestinal disorders	10	0.00 %
Acne pustular	Infections and infestations	10	0.00 %
Adjustment disorder	Psychiatric disorders	10	0.00 %
Adrenal haemorrhage	Endocrine disorders	10	0.00 %
Agonal respiration	Respiratory, thoracic and mediastinal disorders	10	0.00 %
Amblyopia	Eye disorders	10	0.00 %
Amyloidosis	Immune system disorders	10	0.00 %
Anti-thyroid antibody	Investigations	10	0.00 %
Aortic rupture	Vascular disorders	10	0.00 %
Aortic valve disease	Cardiac disorders	10	0.00 %
Appendectomy	Surgical and medical procedures	10	0.00 %
Auditory nerve disorder	Nervous system disorders	10	0.00 %
Bartholin's cyst	Reproductive system and breast disorders	10	0.00 %
Biliary cyst	Hepatobiliary disorders	10	0.00 %
Binge eating	Psychiatric disorders	10	0.00 %
Blood bilirubin decreased	Investigations	10	0.00 %
Blood cholinesterase decreased	Investigations	10	0.00 %
Blood immunoglobulin M decreased	Investigations	10	0.00 %
Blood parathyroid hormone increased	Investigations	10	0.00 %
Blood test	Investigations	10	0.00 %
Breast cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10	0.00 %
Bronchial irritation	Respiratory, thoracic and mediastinal disorders	10	0.00 %
Cardioversion	Surgical and medical procedures	10	0.00 %
Central nervous system infection	Infections and infestations	10	0.00 %
Cerebellar artery thrombosis	Nervous system disorders	10	0.00 %
Cerebral vasoconstriction	Nervous system disorders	10	0.00 %
Choroidal neovascularisation	Eye disorders	10	0.00 %
Compartment syndrome	Musculoskeletal and connective tissue disorders	10	0.00 %
Connective tissue inflammation	Musculoskeletal and connective tissue disorders	10	0.00 %
Corneal oedema	Eye disorders	10	0.00 %
Coronary artery dilatation	Cardiac disorders	10	0.00 %
Cranial nerve palsies multiple	Nervous system disorders	10	0.00 %
Cytokine release syndrome	Immune system disorders	10	0.00 %
Cytomegalovirus hepatitis	Infections and infestations	10	0.00 %
Decidual cast	Pregnancy, puerperium and perinatal conditions	10	0.00 %
Device expulsion	Product issues	10	0.00 %
Differential white blood cell count abnormal	Investigations	10	0.00 %
Dissociative amnesia	Psychiatric disorders	10	0.00 %
Educational problem	Social circumstances	10	0.00 %
Endothelial dysfunction	Vascular disorders	10	0.00 %
Eosinophil percentage increased	Investigations	10	0.00 %
Erythema induratum	Infections and infestations	10	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Erythrosis	Skin and subcutaneous tissue disorders	10	0.00 %
Evans syndrome	Blood and lymphatic system disorders	10	0.00 %
Exposure to vaccinated person	Injury, poisoning and procedural complications	10	0.00 %
Eyelid bleeding	Eye disorders	10	0.00 %
Eyelid contusion	Injury, poisoning and procedural complications	10	0.00 %
Eyelid myoclonus	Eye disorders	10	0.00 %
Faecal vomiting	Gastrointestinal disorders	10	0.00 %
Fibrin D dimer decreased	Investigations	10	0.00 %
Foetal cardiac disorder	Pregnancy, puerperium and perinatal conditions	10	0.00 %
Foetal growth abnormality	Pregnancy, puerperium and perinatal conditions	10	0.00 %
Foetal vascular malperfusion	Pregnancy, puerperium and perinatal conditions	10	0.00 %
Fumbling	Nervous system disorders	10	0.00 %
Gamma-glutamyltransferase abnormal	Investigations	10	0.00 %
Genital hypoesthesia	Reproductive system and breast disorders	10	0.00 %
Gliosis	Nervous system disorders	10	0.00 %
Groin abscess	Infections and infestations	10	0.00 %
Growing pains	Musculoskeletal and connective tissue disorders	10	0.00 %
Haptoglobin decreased	Investigations	10	0.00 %
Helicobacter test positive	Investigations	10	0.00 %
Hirsutism	Skin and subcutaneous tissue disorders	10	0.00 %
Hypermobility syndrome	Musculoskeletal and connective tissue disorders	10	0.00 %
Hyperplasia	General disorders and administration site conditions	10	0.00 %
Idiopathic urticaria	Skin and subcutaneous tissue disorders	10	0.00 %
Inadequate analgesia	General disorders and administration site conditions	10	0.00 %
Infectious thyroiditis	Infections and infestations	10	0.00 %
Infusion site mobility decreased	General disorders and administration site conditions	10	0.00 %
Injection site nodule	General disorders and administration site conditions	10	0.00 %
Injection site vesicles	General disorders and administration site conditions	10	0.00 %
Intraocular pressure test	Investigations	10	0.00 %
Intrauterine contraception	Surgical and medical procedures	10	0.00 %
Joint hyperextension	Musculoskeletal and connective tissue disorders	10	0.00 %
Keloid scar	Skin and subcutaneous tissue disorders	10	0.00 %
Lid sulcus deepened	Eye disorders	10	0.00 %
Ligamentitis	Musculoskeletal and connective tissue disorders	10	0.00 %
Limb operation	Surgical and medical procedures	10	0.00 %
Lung adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10	0.00 %
Macrocytosis	Blood and lymphatic system disorders	10	0.00 %
Mean cell volume abnormal	Investigations	10	0.00 %
Morbid thoughts	Psychiatric disorders	10	0.00 %
Mucosal ulceration	General disorders and administration site conditions	10	0.00 %
Mycoplasma test positive	Investigations	10	0.00 %
Nail ridging	Skin and subcutaneous tissue disorders	10	0.00 %
Nasal ulcer	Respiratory, thoracic and mediastinal disorders	10	0.00 %
Necrotising retinitis	Eye disorders	10	0.00 %
Nephritic syndrome	Renal and urinary disorders	10	0.00 %
Nitrite urine present	Investigations	10	0.00 %
Oscillopsia	Eye disorders	10	0.00 %
Palate injury	Injury, poisoning and procedural complications	10	0.00 %
Penile erythema	Reproductive system and breast disorders	10	0.00 %
Penile vein thrombosis	Reproductive system and breast disorders	10	0.00 %
Peptic ulcer	Gastrointestinal disorders	10	0.00 %
Periorbital cellulitis	Infections and infestations	10	0.00 %
Peripheral artery aneurysm	Vascular disorders	10	0.00 %
Pharyngotonsillitis	Infections and infestations	10	0.00 %
Polychondritis	Musculoskeletal and connective tissue disorders	10	0.00 %
Presbyopia	Eye disorders	10	0.00 %
Product packaging confusion	Injury, poisoning and procedural complications	10	0.00 %
Product reconstitution quality issue	Product issues	10	0.00 %
Puncture site swelling	General disorders and administration site conditions	10	0.00 %
Red blood cell count abnormal	Investigations	10	0.00 %
Red ear syndrome	Ear and labyrinth disorders	10	0.00 %
Renal ischaemia	Renal and urinary disorders	10	0.00 %
Respiratory depth decreased	Respiratory, thoracic and mediastinal disorders	10	0.00 %
Retinitis	Infections and infestations	10	0.00 %
Scarlet fever	Infections and infestations	10	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Sciatic nerve neuropathy	Nervous system disorders	10	0.00 %
Scleral haemorrhage	Eye disorders	10	0.00 %
Scrotal erythema	Reproductive system and breast disorders	10	0.00 %
Secondary hypertension	Vascular disorders	10	0.00 %
Sinusitis bacterial	Infections and infestations	10	0.00 %
Skin discharge	Skin and subcutaneous tissue disorders	10	0.00 %
Skin laxity	Skin and subcutaneous tissue disorders	10	0.00 %
Small for dates baby	Pregnancy, puerperium and perinatal conditions	10	0.00 %
Solar urticaria	Skin and subcutaneous tissue disorders	10	0.00 %
Spondyloarthropathy	Musculoskeletal and connective tissue disorders	10	0.00 %
Spontaneous haemorrhage	Blood and lymphatic system disorders	10	0.00 %
Staphylococcus test positive	Investigations	10	0.00 %
Stress fracture	Injury, poisoning and procedural complications	10	0.00 %
Subclavian artery thrombosis	Vascular disorders	10	0.00 %
Target skin lesion	Skin and subcutaneous tissue disorders	10	0.00 %
Temporal lobe epilepsy	Nervous system disorders	10	0.00 %
Testis cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10	0.00 %
Thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10	0.00 %
Tinea infection	Infections and infestations	10	0.00 %
Tongue exfoliation	Gastrointestinal disorders	10	0.00 %
Toxic shock syndrome	Infections and infestations	10	0.00 %
Transient acantholytic dermatosis	Skin and subcutaneous tissue disorders	10	0.00 %
Tri-iodothyronine increased	Investigations	10	0.00 %
Urinary straining	Renal and urinary disorders	10	0.00 %
Vaginal cyst	Reproductive system and breast disorders	10	0.00 %
Visual perseveration	Nervous system disorders	10	0.00 %
Warm type haemolytic anaemia	Blood and lymphatic system disorders	10	0.00 %
Weight loss poor	Metabolism and nutrition disorders	10	0.00 %
Xerophthalmia	Eye disorders	10	0.00 %
Abnormal sleep-related event	Psychiatric disorders	9	0.00 %
Abortion threatened	Pregnancy, puerperium and perinatal conditions	9	0.00 %
Abscess neck	Infections and infestations	9	0.00 %
Acrochordon	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Adrenal adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Allergy to metals	Immune system disorders	9	0.00 %
Amnorrhoea	Pregnancy, puerperium and perinatal conditions	9	0.00 %
Angiotensin converting enzyme increased	Investigations	9	0.00 %
Anisocytosis	Blood and lymphatic system disorders	9	0.00 %
Anorgasmia	Psychiatric disorders	9	0.00 %
Anticoagulation drug level below therapeutic	Investigations	9	0.00 %
Arteriovenous fistula	Vascular disorders	9	0.00 %
Autoimmune neutropenia	Blood and lymphatic system disorders	9	0.00 %
Bartholinitis	Infections and infestations	9	0.00 %
Basal ganglia stroke	Nervous system disorders	9	0.00 %
Beta 2 microglobulin increased	Investigations	9	0.00 %
Bile acid malabsorption	Gastrointestinal disorders	9	0.00 %
Blood ketone body increased	Investigations	9	0.00 %
Blood lactate dehydrogenase decreased	Investigations	9	0.00 %
Blood potassium abnormal	Investigations	9	0.00 %
Booster dose missed	Injury, poisoning and procedural complications	9	0.00 %
Brachiocephalic vein thrombosis	Vascular disorders	9	0.00 %
Burn of internal organs	Injury, poisoning and procedural complications	9	0.00 %
Burns third degree	Injury, poisoning and procedural complications	9	0.00 %
Calculus bladder	Renal and urinary disorders	9	0.00 %
CD4 lymphocytes decreased	Investigations	9	0.00 %
Cerumen impaction	Ear and labyrinth disorders	9	0.00 %
Cervix disorder	Reproductive system and breast disorders	9	0.00 %
Claudication of jaw muscles	Vascular disorders	9	0.00 %
Coagulation time shortened	Investigations	9	0.00 %
Complication of pregnancy	Pregnancy, puerperium and perinatal conditions	9	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Compression fracture	Injury, poisoning and procedural complications	9	0.00 %
Contraindication to vaccination	Social circumstances	9	0.00 %
Corneal abrasion	Injury, poisoning and procedural complications	9	0.00 %
Corneal bleeding	Eye disorders	9	0.00 %
Coronavirus pneumonia	Infections and infestations	9	0.00 %
Costovertebral angle tenderness	Renal and urinary disorders	9	0.00 %
Cystitis bacterial	Infections and infestations	9	0.00 %
Deja vu	Psychiatric disorders	9	0.00 %
Dermatochalasis	Eye disorders	9	0.00 %
Device breakage	Product issues	9	0.00 %
Disinhibition	Psychiatric disorders	9	0.00 %
Echocardiogram normal	Investigations	9	0.00 %
Electrocardiogram ST-T segment abnormal	Investigations	9	0.00 %
Electromagnetic interference	Product issues	9	0.00 %
Empyema	Infections and infestations	9	0.00 %
Encephalomalacia	Nervous system disorders	9	0.00 %
Eyelid exfoliation	Eye disorders	9	0.00 %
False positive investigation result	Investigations	9	0.00 %
Female reproductive tract disorder	Reproductive system and breast disorders	9	0.00 %
Foreign body	Injury, poisoning and procedural complications	9	0.00 %
Gallbladder oedema	Hepatobiliary disorders	9	0.00 %
Gamma-glutamyltransferase decreased	Investigations	9	0.00 %
Gastrointestinal carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Genital infection fungal	Infections and infestations	9	0.00 %
Gestational hypertension	Pregnancy, puerperium and perinatal conditions	9	0.00 %
Haematocrit abnormal	Investigations	9	0.00 %
Haemophilia	Congenital, familial and genetic disorders	9	0.00 %
Hair injury	Injury, poisoning and procedural complications	9	0.00 %
Head lag	Investigations	9	0.00 %
Hepatic haemorrhage	Hepatobiliary disorders	9	0.00 %
Hepatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Hepatocellular carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Heterophoria	Eye disorders	9	0.00 %
Hip arthroplasty	Surgical and medical procedures	9	0.00 %
Huntington's disease	Congenital, familial and genetic disorders	9	0.00 %
Hypereosinophilic syndrome	Blood and lymphatic system disorders	9	0.00 %
Hypergeusia	Nervous system disorders	9	0.00 %
Hypnagogic hallucination	Psychiatric disorders	9	0.00 %
Hypochromic anaemia	Blood and lymphatic system disorders	9	0.00 %
Iliac artery occlusion	Vascular disorders	9	0.00 %
Imperception	Psychiatric disorders	9	0.00 %
Incision site pain	Injury, poisoning and procedural complications	9	0.00 %
Incorrect product administration duration	Injury, poisoning and procedural complications	9	0.00 %
Inferior vena cava dilatation	Vascular disorders	9	0.00 %
Intention tremor	Nervous system disorders	9	0.00 %
Intestinal dilatation	Gastrointestinal disorders	9	0.00 %
Intracranial mass	Nervous system disorders	9	0.00 %
Kaposi's sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Laryngeal dyspnoea	Respiratory, thoracic and mediastinal disorders	9	0.00 %
Light chain analysis increased	Investigations	9	0.00 %
Lip erosion	Gastrointestinal disorders	9	0.00 %
Loss of bladder sensation	Renal and urinary disorders	9	0.00 %
Lower gastrointestinal haemorrhage	Gastrointestinal disorders	9	0.00 %
Lower motor neurone lesion	Nervous system disorders	9	0.00 %
Lower urinary tract symptoms	Renal and urinary disorders	9	0.00 %
Lumbar puncture	Investigations	9	0.00 %
Malocclusion	Gastrointestinal disorders	9	0.00 %
Mean arterial pressure increased	Investigations	9	0.00 %
Meningitis herpes	Infections and infestations	9	0.00 %
Meningorrhagia	Nervous system disorders	9	0.00 %
Morose	Psychiatric disorders	9	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Muscle contusion	Injury, poisoning and procedural complications	9	0.00 %
Myocardial hypoxia	Cardiac disorders	9	0.00 %
Nail psoriasis	Skin and subcutaneous tissue disorders	9	0.00 %
Neutrophilic dermatosis	Skin and subcutaneous tissue disorders	9	0.00 %
Nodal rhythm	Cardiac disorders	9	0.00 %
Nonspecific reaction	General disorders and administration site conditions	9	0.00 %
Obstructive pancreatitis	Gastrointestinal disorders	9	0.00 %
Oesophageal stenosis	Gastrointestinal disorders	9	0.00 %
Opisthotonus	Nervous system disorders	9	0.00 %
Optic atrophy	Eye disorders	9	0.00 %
Organic brain syndrome	Psychiatric disorders	9	0.00 %
Oropharyngeal candidiasis	Infections and infestations	9	0.00 %
Oxygen saturation immeasurable	Investigations	9	0.00 %
Patella fracture	Injury, poisoning and procedural complications	9	0.00 %
Periorbital haemorrhage	Injury, poisoning and procedural complications	9	0.00 %
Periphlebitis	Vascular disorders	9	0.00 %
Peyronie's disease	Reproductive system and breast disorders	9	0.00 %
Pharyngitis bacterial	Infections and infestations	9	0.00 %
Pleural disorder	Respiratory, thoracic and mediastinal disorders	9	0.00 %
Prohormone brain natriuretic peptide increased	Investigations	9	0.00 %
Prolonged expiration	Respiratory, thoracic and mediastinal disorders	9	0.00 %
Prostate infection	Infections and infestations	9	0.00 %
Prostatic specific antigen decreased	Investigations	9	0.00 %
Prothrombin time ratio increased	Investigations	9	0.00 %
Pulse pressure decreased	Investigations	9	0.00 %
Rash papulosquamous	Skin and subcutaneous tissue disorders	9	0.00 %
Relapsing multiple sclerosis	Nervous system disorders	9	0.00 %
Repetitive speech	Nervous system disorders	9	0.00 %
Retrograde menstruation	Reproductive system and breast disorders	9	0.00 %
Right atrial enlargement	Cardiac disorders	9	0.00 %
Rubella	Infections and infestations	9	0.00 %
Salivary gland neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	0.00 %
Scalloped tongue	Gastrointestinal disorders	9	0.00 %
Segmented hyalinising vasculitis	Skin and subcutaneous tissue disorders	9	0.00 %
Seroma	Injury, poisoning and procedural complications	9	0.00 %
Smear cervix abnormal	Investigations	9	0.00 %
Social anxiety disorder	Psychiatric disorders	9	0.00 %
Soft tissue injury	Injury, poisoning and procedural complications	9	0.00 %
Splenic artery thrombosis	Blood and lymphatic system disorders	9	0.00 %
Stasis dermatitis	Skin and subcutaneous tissue disorders	9	0.00 %
Status asthmaticus	Respiratory, thoracic and mediastinal disorders	9	0.00 %
Stent placement	Surgical and medical procedures	9	0.00 %
Stomach mass	Gastrointestinal disorders	9	0.00 %
T-lymphocyte count increased	Investigations	9	0.00 %
Testicular torsion	Reproductive system and breast disorders	9	0.00 %
Tracheal disorder	Respiratory, thoracic and mediastinal disorders	9	0.00 %
Tracheal obstruction	Injury, poisoning and procedural complications	9	0.00 %
Urticaria pressure	Skin and subcutaneous tissue disorders	9	0.00 %
Vaccination site erosion	General disorders and administration site conditions	9	0.00 %
Vaccination site hypertrophy	General disorders and administration site conditions	9	0.00 %
Vaccination site pallor	General disorders and administration site conditions	9	0.00 %
Varicose vein ruptured	Vascular disorders	9	0.00 %
Ventricular enlargement	Cardiac disorders	9	0.00 %
Vertigo CNS origin	Nervous system disorders	9	0.00 %
VIIth nerve injury	Injury, poisoning and procedural complications	9	0.00 %
Visual pathway disorder	Nervous system disorders	9	0.00 %
Acetonaemia	Metabolism and nutrition disorders	8	0.00 %
Actinic keratosis	Skin and subcutaneous tissue disorders	8	0.00 %
Acute aseptic arthritis	Musculoskeletal and connective tissue disorders	8	0.00 %
Administration site lymphadenopathy	General disorders and administration site conditions	8	0.00 %
Adnexal torsion	Reproductive system and breast disorders	8	0.00 %
Adrenal mass	Endocrine disorders	8	0.00 %
African trypanosomiasis	Infections and infestations	8	0.00 %
Agitated depression	Psychiatric disorders	8	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Alexia	Nervous system disorders	8	0.00 %
Alkalosis	Metabolism and nutrition disorders	8	0.00 %
Amniorrhesis	Pregnancy, puerperium and perinatal conditions	8	0.00 %
Amniotic fluid volume decreased	Investigations	8	0.00 %
Anaphylactoid shock	Immune system disorders	8	0.00 %
Aortic occlusion	Vascular disorders	8	0.00 %
Aortic valve sclerosis	Cardiac disorders	8	0.00 %
Apnoeic attack	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Application site induration	General disorders and administration site conditions	8	0.00 %
Autoimmune anaemia	Blood and lymphatic system disorders	8	0.00 %
Autonomic dysreflexia	Injury, poisoning and procedural complications	8	0.00 %
Bacteriuria	Infections and infestations	8	0.00 %
Barotrauma	Injury, poisoning and procedural complications	8	0.00 %
Barrett's oesophagus	Gastrointestinal disorders	8	0.00 %
Benign familial pemphigus	Congenital, familial and genetic disorders	8	0.00 %
Biliary tract disorder	Hepatobiliary disorders	8	0.00 %
Bladder catheterisation	Surgical and medical procedures	8	0.00 %
Blood electrolytes decreased	Investigations	8	0.00 %
Blood iron abnormal	Investigations	8	0.00 %
Blood testosterone increased	Investigations	8	0.00 %
Blood triglycerides abnormal	Investigations	8	0.00 %
Blood urea abnormal	Investigations	8	0.00 %
Blood uric acid decreased	Investigations	8	0.00 %
Body mass index increased	Investigations	8	0.00 %
Breakthrough pain	General disorders and administration site conditions	8	0.00 %
Breast discolouration	Reproductive system and breast disorders	8	0.00 %
Brown-Sequard syndrome	Nervous system disorders	8	0.00 %
Bulbar palsy	Nervous system disorders	8	0.00 %
Capsular contracture associated with breast implant	General disorders and administration site conditions	8	0.00 %
Carbon dioxide increased	Investigations	8	0.00 %
Cardiac amyloidosis	Cardiac disorders	8	0.00 %
Cardio-respiratory distress	Cardiac disorders	8	0.00 %
Cardiothoracic ratio increased	Investigations	8	0.00 %
Carotid artery aneurysm	Nervous system disorders	8	0.00 %
Catheterisation cardiac	Investigations	8	0.00 %
Chlamydial infection	Infections and infestations	8	0.00 %
Chloasma	Skin and subcutaneous tissue disorders	8	0.00 %
Chronic cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	8	0.00 %
Coagulation factor increased	Investigations	8	0.00 %
Coagulation factor VIII level increased	Investigations	8	0.00 %
Conductive deafness	Ear and labyrinth disorders	8	0.00 %
Contrast media allergy	Immune system disorders	8	0.00 %
CSF pressure increased	Investigations	8	0.00 %
Cystitis escherichia	Infections and infestations	8	0.00 %
Decreased insulin requirement	Metabolism and nutrition disorders	8	0.00 %
Dermabrasion	Surgical and medical procedures	8	0.00 %
Diarrhoea neonatal	Gastrointestinal disorders	8	0.00 %
Diffuse alveolar damage	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Diplacusis	Ear and labyrinth disorders	8	0.00 %
Disturbance in social behaviour	Psychiatric disorders	8	0.00 %
Dressler's syndrome	Cardiac disorders	8	0.00 %
Drug level increased	Investigations	8	0.00 %
Drug withdrawal syndrome	General disorders and administration site conditions	8	0.00 %
Dust allergy	Immune system disorders	8	0.00 %
Ectropion of cervix	Reproductive system and breast disorders	8	0.00 %
Eczema vesicular	Skin and subcutaneous tissue disorders	8	0.00 %
Electrocardiogram Q wave abnormal	Investigations	8	0.00 %
Epidermal necrosis	Skin and subcutaneous tissue disorders	8	0.00 %
Epiploic appendagitis	Gastrointestinal disorders	8	0.00 %
Erythropsia	Eye disorders	8	0.00 %
Eschar	Injury, poisoning and procedural complications	8	0.00 %
Factor VIII deficiency	Congenital, familial and genetic disorders	8	0.00 %
Fluid imbalance	Metabolism and nutrition disorders	8	0.00 %
Foetal heart rate decreased	Investigations	8	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Follicular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8	0.00 %
Fungal test positive	Investigations	8	0.00 %
Gallbladder polyp	Hepatobiliary disorders	8	0.00 %
Gastric cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8	0.00 %
Gene mutation	Congenital, familial and genetic disorders	8	0.00 %
Genital abscess	Infections and infestations	8	0.00 %
Genital discharge	Reproductive system and breast disorders	8	0.00 %
Graft versus host disease	Immune system disorders	8	0.00 %
Granulocyte count decreased	Investigations	8	0.00 %
Haemoglobinuria	Renal and urinary disorders	8	0.00 %
Haemorrhagic cyst	General disorders and administration site conditions	8	0.00 %
Hand-eye coordination impaired	Nervous system disorders	8	0.00 %
Hepatitis fulminant	Hepatobiliary disorders	8	0.00 %
Hepatojugular reflux	Cardiac disorders	8	0.00 %
Hydrops foetalis	Pregnancy, puerperium and perinatal conditions	8	0.00 %
Hyperfibrinogenaemia	Blood and lymphatic system disorders	8	0.00 %
Hyperglycaemic hyperosmolar nonketotic syndrome	Metabolism and nutrition disorders	8	0.00 %
Hyperparathyroidism	Endocrine disorders	8	0.00 %
Hyperproteinæmia	Metabolism and nutrition disorders	8	0.00 %
Hypomania	Psychiatric disorders	8	0.00 %
Illness anxiety disorder	Psychiatric disorders	8	0.00 %
Immunoglobulin G4 related disease	Musculoskeletal and connective tissue disorders	8	0.00 %
Immunology test abnormal	Investigations	8	0.00 %
Impaired fasting glucose	Metabolism and nutrition disorders	8	0.00 %
Infection parasitic	Infections and infestations	8	0.00 %
Infective exacerbation of chronic obstructive airways disease	Infections and infestations	8	0.00 %
Intertrigo	Skin and subcutaneous tissue disorders	8	0.00 %
Intestinal ulcer	Gastrointestinal disorders	8	0.00 %
Intranasal hypoesthesia	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Irregular sleep phase	Nervous system disorders	8	0.00 %
Kidney transplant rejection	Immune system disorders	8	0.00 %
Latent autoimmune diabetes in adults	Metabolism and nutrition disorders	8	0.00 %
Left ventricular enlargement	Cardiac disorders	8	0.00 %
Liver function test decreased	Investigations	8	0.00 %
Lung diffusion disorder	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Lymphocyte percentage increased	Investigations	8	0.00 %
Lymphoid tissue hyperplasia	Blood and lymphatic system disorders	8	0.00 %
Masticatory pain	Musculoskeletal and connective tissue disorders	8	0.00 %
May-Thurner syndrome	Vascular disorders	8	0.00 %
Meningoencephalitis viral	Infections and infestations	8	0.00 %
Microangiopathic haemolytic anaemia	Blood and lymphatic system disorders	8	0.00 %
Micturition frequency decreased	Renal and urinary disorders	8	0.00 %
Monocyte count abnormal	Investigations	8	0.00 %
Morton's neuralgia	Nervous system disorders	8	0.00 %
Mucosal pain	General disorders and administration site conditions	8	0.00 %
Muscle tone disorder	Nervous system disorders	8	0.00 %
Myofascitis	Musculoskeletal and connective tissue disorders	8	0.00 %
Nail bed bleeding	Skin and subcutaneous tissue disorders	8	0.00 %
Nail growth abnormal	Skin and subcutaneous tissue disorders	8	0.00 %
Nasal odour	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Neurodegenerative disorder	Nervous system disorders	8	0.00 %
Neutrophil percentage decreased	Investigations	8	0.00 %
Nipple exudate bloody	Reproductive system and breast disorders	8	0.00 %
Obsessive thoughts	Psychiatric disorders	8	0.00 %
Oesophageal candidiasis	Infections and infestations	8	0.00 %
Oesophageal oedema	Gastrointestinal disorders	8	0.00 %
Oesophageal varices haemorrhage	Gastrointestinal disorders	8	0.00 %
Oestradiol increased	Investigations	8	0.00 %
Oligodipsia	Metabolism and nutrition disorders	8	0.00 %
Oral mucosal discolouration	Gastrointestinal disorders	8	0.00 %
Oral papule	Gastrointestinal disorders	8	0.00 %
Osteoarthropathy	Musculoskeletal and connective tissue disorders	8	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Painful erection	Reproductive system and breast disorders	8	0.00 %
Paroxysmal nocturnal haemoglobinuria	Renal and urinary disorders	8	0.00 %
Pericardial drainage	Surgical and medical procedures	8	0.00 %
Peripheral artery stenosis	Vascular disorders	8	0.00 %
Pernicious anaemia	Blood and lymphatic system disorders	8	0.00 %
Persecutory delusion	Psychiatric disorders	8	0.00 %
pH urine increased	Investigations	8	0.00 %
Pilonidal cyst	Infections and infestations	8	0.00 %
Pneumonia mycoplasmal	Infections and infestations	8	0.00 %
Portal hypertension	Hepatobiliary disorders	8	0.00 %
Post procedural diarrhoea	Injury, poisoning and procedural complications	8	0.00 %
Postmenopause	Social circumstances	8	0.00 %
Pregnancy on contraceptive	Pregnancy, puerperium and perinatal conditions	8	0.00 %
Product confusion	Injury, poisoning and procedural complications	8	0.00 %
Product dose omission in error	Injury, poisoning and procedural complications	8	0.00 %
Product odour abnormal	Product issues	8	0.00 %
Product use complaint	Injury, poisoning and procedural complications	8	0.00 %
Prolonged pregnancy	Pregnancy, puerperium and perinatal conditions	8	0.00 %
Prostatic pain	Reproductive system and breast disorders	8	0.00 %
Psychiatric decompensation	Psychiatric disorders	8	0.00 %
Pulmonary granuloma	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Pyuria	Infections and infestations	8	0.00 %
QRS axis abnormal	Investigations	8	0.00 %
Rash maculovesicular	Skin and subcutaneous tissue disorders	8	0.00 %
Rectal prolapse	Gastrointestinal disorders	8	0.00 %
Renal atrophy	Renal and urinary disorders	8	0.00 %
Renal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8	0.00 %
Reticulocyte count increased	Investigations	8	0.00 %
Rheumatoid nodule	Musculoskeletal and connective tissue disorders	8	0.00 %
Roseola	Infections and infestations	8	0.00 %
Salt craving	Metabolism and nutrition disorders	8	0.00 %
Seborrhoeic keratosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8	0.00 %
Sedation complication	Injury, poisoning and procedural complications	8	0.00 %
Seizure cluster	Nervous system disorders	8	0.00 %
Serum ferritin abnormal	Investigations	8	0.00 %
Shoulder deformity	Musculoskeletal and connective tissue disorders	8	0.00 %
Sinoatrial block	Cardiac disorders	8	0.00 %
Stiff leg syndrome	Nervous system disorders	8	0.00 %
Stiff person syndrome	Nervous system disorders	8	0.00 %
Stroke in evolution	Nervous system disorders	8	0.00 %
Subacute cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	8	0.00 %
Subcutaneous emphysema	Skin and subcutaneous tissue disorders	8	0.00 %
Suspected product quality issue	Product issues	8	0.00 %
Takayasu's arteritis	Vascular disorders	8	0.00 %
Temperature perception test abnormal	Investigations	8	0.00 %
Thymus disorder	Blood and lymphatic system disorders	8	0.00 %
Tissue injury	Injury, poisoning and procedural complications	8	0.00 %
Tongue fungal infection	Infections and infestations	8	0.00 %
Transfusion	Surgical and medical procedures	8	0.00 %
Tri-iodothyronine free increased	Investigations	8	0.00 %
Trigeminal nerve paresis	Nervous system disorders	8	0.00 %
Unmasking of previously unidentified disease	General disorders and administration site conditions	8	0.00 %
Unwanted pregnancy	Pregnancy, puerperium and perinatal conditions	8	0.00 %
Upper respiratory tract irritation	Respiratory, thoracic and mediastinal disorders	8	0.00 %
Ureterolithiasis	Renal and urinary disorders	8	0.00 %
Urethral haemorrhage	Renal and urinary disorders	8	0.00 %
Urinary tract obstruction	Renal and urinary disorders	8	0.00 %
Urobilinogen urine increased	Investigations	8	0.00 %
Urticarial dermatitis	Skin and subcutaneous tissue disorders	8	0.00 %
Uterine infection	Infections and infestations	8	0.00 %
Vaccine induced antibody absent	Investigations	8	0.00 %
Varices oesophageal	Gastrointestinal disorders	8	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vascular calcification	Vascular disorders	8	0.00 %
Venous oxygen saturation decreased	Investigations	8	0.00 %
Vestibulitis	Infections and infestations	8	0.00 %
VIIth nerve injury	Injury, poisoning and procedural complications	8	0.00 %
Vital functions abnormal	Investigations	8	0.00 %
Vitreous haze	Eye disorders	8	0.00 %
Vulval oedema	Reproductive system and breast disorders	8	0.00 %
Abdominal adhesions	Gastrointestinal disorders	7	0.00 %
Abortion late	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Abortion spontaneous complete	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Abscess drainage	Surgical and medical procedures	7	0.00 %
Abscess intestinal	Infections and infestations	7	0.00 %
Accelerated hypertension	Vascular disorders	7	0.00 %
Action tremor	Nervous system disorders	7	0.00 %
Activated partial thromboplastin time ratio decreased	Investigations	7	0.00 %
Acute motor-sensory axonal neuropathy	Nervous system disorders	7	0.00 %
Acute myeloid leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Administration site pruritus	General disorders and administration site conditions	7	0.00 %
Adrenomegaly	Endocrine disorders	7	0.00 %
Airway burns	Injury, poisoning and procedural complications	7	0.00 %
Albumin urine present	Investigations	7	0.00 %
Aldolase increased	Investigations	7	0.00 %
Allergy to plants	Immune system disorders	7	0.00 %
Anencephaly	Congenital, familial and genetic disorders	7	0.00 %
Angina bullosa haemorrhagica	Gastrointestinal disorders	7	0.00 %
Anion gap decreased	Investigations	7	0.00 %
Anisomastia	Reproductive system and breast disorders	7	0.00 %
Anosognosia	Nervous system disorders	7	0.00 %
Anti-GAD antibody positive	Investigations	7	0.00 %
Anti-Muellerian hormone level decreased	Investigations	7	0.00 %
Aortic dissection rupture	Vascular disorders	7	0.00 %
Application site bruise	General disorders and administration site conditions	7	0.00 %
Application site haemorrhage	General disorders and administration site conditions	7	0.00 %
Arnold-Chiari malformation	Congenital, familial and genetic disorders	7	0.00 %
Arteriovenous fistula thrombosis	Injury, poisoning and procedural complications	7	0.00 %
Arteriovenous malformation	Congenital, familial and genetic disorders	7	0.00 %
Atrial enlargement	Cardiac disorders	7	0.00 %
Autoimmune hypothyroidism	Endocrine disorders	7	0.00 %
Axillary nerve injury	Injury, poisoning and procedural complications	7	0.00 %
Ballismus	Nervous system disorders	7	0.00 %
Bleeding varicose vein	Vascular disorders	7	0.00 %
Blood cholinesterase increased	Investigations	7	0.00 %
Blood creatine decreased	Investigations	7	0.00 %
Blood fibrinogen abnormal	Investigations	7	0.00 %
Blood lactate dehydrogenase abnormal	Investigations	7	0.00 %
Blood luteinising hormone increased	Investigations	7	0.00 %
Blood pH decreased	Investigations	7	0.00 %
Blood pressure systolic	Investigations	7	0.00 %
Blood pressure systolic abnormal	Investigations	7	0.00 %
Blood sodium abnormal	Investigations	7	0.00 %
Blood zinc decreased	Investigations	7	0.00 %
Bradycardia foetal	Cardiac disorders	7	0.00 %
Brain scan abnormal	Investigations	7	0.00 %
Breath holding	Psychiatric disorders	7	0.00 %
Bronchitis viral	Infections and infestations	7	0.00 %
Carbohydrate antigen 15-3 increased	Investigations	7	0.00 %
Cardiac stress test abnormal	Investigations	7	0.00 %
Cardiac ventricular disorder	Cardiac disorders	7	0.00 %
Cardiorenal syndrome	Cardiac disorders	7	0.00 %
Cellulite	Skin and subcutaneous tissue disorders	7	0.00 %
Cerebellar atrophy	Nervous system disorders	7	0.00 %
Cervix carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Chemical burn of skin	Injury, poisoning and procedural complications	7	0.00 %
Chest wall mass	Musculoskeletal and connective tissue disorders	7	0.00 %
Chest X-ray	Investigations	7	0.00 %
Chondritis	Musculoskeletal and connective tissue disorders	7	0.00 %
Choroiditis	Eye disorders	7	0.00 %
Circumstance or information capable of leading to device use error	Injury, poisoning and procedural complications	7	0.00 %
Cold type haemolytic anaemia	Blood and lymphatic system disorders	7	0.00 %
Complement factor C3 decreased	Investigations	7	0.00 %
Constricted affect	Psychiatric disorders	7	0.00 %
Corneal dystrophy	Congenital, familial and genetic disorders	7	0.00 %
Coxsackie viral infection	Infections and infestations	7	0.00 %
CSF immunoglobulin increased	Investigations	7	0.00 %
Culture urine positive	Investigations	7	0.00 %
Cushingoid	Endocrine disorders	7	0.00 %
Delayed menarche	Endocrine disorders	7	0.00 %
Dermoid cyst	Congenital, familial and genetic disorders	7	0.00 %
Diabetic coma	Nervous system disorders	7	0.00 %
Diabetic complication	Metabolism and nutrition disorders	7	0.00 %
Diabetic neuropathy	Nervous system disorders	7	0.00 %
Disseminated varicella zoster virus infection	Infections and infestations	7	0.00 %
Drug resistance	General disorders and administration site conditions	7	0.00 %
Dysdiadochokinesis	Nervous system disorders	7	0.00 %
Eczema infected	Infections and infestations	7	0.00 %
Endotracheal intubation	Surgical and medical procedures	7	0.00 %
Eosinophil count abnormal	Investigations	7	0.00 %
Exercise electrocardiogram abnormal	Investigations	7	0.00 %
Exposure to communicable disease	Injury, poisoning and procedural complications	7	0.00 %
Extradural haematoma	Injury, poisoning and procedural complications	7	0.00 %
Feeding intolerance	Metabolism and nutrition disorders	7	0.00 %
Fever neonatal	General disorders and administration site conditions	7	0.00 %
Fibroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Full blood count increased	Investigations	7	0.00 %
Gastric polyps	Gastrointestinal disorders	7	0.00 %
Gastrointestinal obstruction	Gastrointestinal disorders	7	0.00 %
Gastrointestinal perforation	Gastrointestinal disorders	7	0.00 %
Gastrointestinal viral infection	Infections and infestations	7	0.00 %
Glioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Glossoptosis	Gastrointestinal disorders	7	0.00 %
Granulocyte count increased	Investigations	7	0.00 %
Haematology test abnormal	Investigations	7	0.00 %
Haemolytic uraemic syndrome	Blood and lymphatic system disorders	7	0.00 %
Heart rate normal	Investigations	7	0.00 %
Heart sounds	Investigations	7	0.00 %
Hepatic fibrosis	Hepatobiliary disorders	7	0.00 %
Hepatitis infectious mononucleosis	Infections and infestations	7	0.00 %
Hepatotoxicity	Hepatobiliary disorders	7	0.00 %
Hippocampal atrophy	Nervous system disorders	7	0.00 %
Histamine abnormal	Investigations	7	0.00 %
HIV infection	Infections and infestations	7	0.00 %
HIV test positive	Investigations	7	0.00 %
Holmes-Adie pupil	Eye disorders	7	0.00 %
Hormone therapy	Surgical and medical procedures	7	0.00 %
Hyperemesis gravidarum	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Hyperkinesia	Nervous system disorders	7	0.00 %
Hyperpathia	Nervous system disorders	7	0.00 %
Hypertensive cardiomyopathy	Cardiac disorders	7	0.00 %
Hypochloraemia	Metabolism and nutrition disorders	7	0.00 %
Hypoglossal nerve paralysis	Nervous system disorders	7	0.00 %
Hyposomnia	Psychiatric disorders	7	0.00 %
Immediate post-injection reaction	General disorders and administration site conditions	7	0.00 %
Immune-mediated myositis	Musculoskeletal and connective tissue disorders	7	0.00 %
Immune-mediated neuropathy	Nervous system disorders	7	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Impulse-control disorder	Psychiatric disorders	7	0.00 %
Induced labour	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Infected skin ulcer	Infections and infestations	7	0.00 %
Injection site deformation	General disorders and administration site conditions	7	0.00 %
Injury corneal	Injury, poisoning and procedural complications	7	0.00 %
Inner ear infarction	Ear and labyrinth disorders	7	0.00 %
Intensive care	Surgical and medical procedures	7	0.00 %
Intentional overdose	Injury, poisoning and procedural complications	7	0.00 %
Interleukin-2 receptor increased	Investigations	7	0.00 %
Intervertebral disc space narrowing	Musculoskeletal and connective tissue disorders	7	0.00 %
Intracranial hypotension	Nervous system disorders	7	0.00 %
IVth nerve paresis	Nervous system disorders	7	0.00 %
Large intestinal ulcer	Gastrointestinal disorders	7	0.00 %
Laryngopharyngitis	Infections and infestations	7	0.00 %
Learning disability	Psychiatric disorders	7	0.00 %
Lipase decreased	Investigations	7	0.00 %
Live birth	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Loss of employment	Social circumstances	7	0.00 %
Low birth weight baby	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Low cardiac output syndrome	Cardiac disorders	7	0.00 %
Lymph nodes scan abnormal	Investigations	7	0.00 %
Lymphadenectomy	Surgical and medical procedures	7	0.00 %
Lymphoproliferative disorder	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Meibomian gland dysfunction	Eye disorders	7	0.00 %
Meningitis pneumococcal	Infections and infestations	7	0.00 %
Menopausal disorder	Reproductive system and breast disorders	7	0.00 %
Metabolic encephalopathy	Nervous system disorders	7	0.00 %
Microcytosis	Blood and lymphatic system disorders	7	0.00 %
Microvascular coronary artery disease	Cardiac disorders	7	0.00 %
Mineral metabolism disorder	Metabolism and nutrition disorders	7	0.00 %
Mitral valve calcification	Cardiac disorders	7	0.00 %
Mononucleosis syndrome	Infections and infestations	7	0.00 %
Multiple sclerosis pseudo relapse	Nervous system disorders	7	0.00 %
Muscle necrosis	Musculoskeletal and connective tissue disorders	7	0.00 %
Muscular dystrophy	Congenital, familial and genetic disorders	7	0.00 %
Myelin oligodendrocyte glycoprotein antibody-associated disease	Nervous system disorders	7	0.00 %
Myeloproliferative neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Myocardial strain imaging	Investigations	7	0.00 %
Myocarditis infectious	Infections and infestations	7	0.00 %
Nail bed inflammation	Skin and subcutaneous tissue disorders	7	0.00 %
Nasal septum deviation	Respiratory, thoracic and mediastinal disorders	7	0.00 %
Nasal turbinate hypertrophy	Respiratory, thoracic and mediastinal disorders	7	0.00 %
Neonatal seizure	Nervous system disorders	7	0.00 %
Nephrosclerosis	Renal and urinary disorders	7	0.00 %
Nerve degeneration	Nervous system disorders	7	0.00 %
Neuroleptic malignant syndrome	Nervous system disorders	7	0.00 %
Neurotoxicity	Nervous system disorders	7	0.00 %
Ocular rosacea	Eye disorders	7	0.00 %
Ocular vasculitis	Eye disorders	7	0.00 %
Oculofacial paralysis	Nervous system disorders	7	0.00 %
Oesophageal ulcer	Gastrointestinal disorders	7	0.00 %
Optic disc haemorrhage	Eye disorders	7	0.00 %
Oxygen therapy	Surgical and medical procedures	7	0.00 %
Pancreatic steatosis	Gastrointestinal disorders	7	0.00 %
Papillitis	General disorders and administration site conditions	7	0.00 %
Parainfluenzae virus infection	Infections and infestations	7	0.00 %
Parakeratosis	Skin and subcutaneous tissue disorders	7	0.00 %
Paramnesia	Psychiatric disorders	7	0.00 %
Parasomnia	Psychiatric disorders	7	0.00 %
Paternal exposure during pregnancy	Injury, poisoning and procedural complications	7	0.00 %
Pathogen resistance	Infections and infestations	7	0.00 %
Pelvic floor muscle weakness	Reproductive system and breast disorders	7	0.00 %
Penile blister	Reproductive system and breast disorders	7	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Penile rash	Reproductive system and breast disorders	7	0.00 %
Perforation	General disorders and administration site conditions	7	0.00 %
Pharyngeal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Placental insufficiency	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Plantar fascial fibromatosis	Musculoskeletal and connective tissue disorders	7	0.00 %
Pneumococcal infection	Infections and infestations	7	0.00 %
Pneumonia pseudomonad	Infections and infestations	7	0.00 %
Pneumonia streptococcal	Infections and infestations	7	0.00 %
PO2 increased	Investigations	7	0.00 %
Polycythaemia vera	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Post concussion syndrome	Injury, poisoning and procedural complications	7	0.00 %
Presbyacusis	Ear and labyrinth disorders	7	0.00 %
Procedural haemorrhage	Injury, poisoning and procedural complications	7	0.00 %
Product administration interrupted	Injury, poisoning and procedural complications	7	0.00 %
Product container issue	Product issues	7	0.00 %
Product container seal issue	Product issues	7	0.00 %
Product deposit	Product issues	7	0.00 %
Protein total abnormal	Investigations	7	0.00 %
Prothrombin level increased	Investigations	7	0.00 %
Prothrombin time abnormal	Investigations	7	0.00 %
Pulmonary toxicity	Respiratory, thoracic and mediastinal disorders	7	0.00 %
Reflux laryngitis	Respiratory, thoracic and mediastinal disorders	7	0.00 %
Renal abscess	Infections and infestations	7	0.00 %
Renal embolism	Renal and urinary disorders	7	0.00 %
Reproductive tract disorder	Reproductive system and breast disorders	7	0.00 %
Rubber sensitivity	Immune system disorders	7	0.00 %
Salmonellosis	Infections and infestations	7	0.00 %
SARS-CoV-2 test	Investigations	7	0.00 %
Scrotal oedema	Reproductive system and breast disorders	7	0.00 %
Silent thyroiditis	Endocrine disorders	7	0.00 %
Small cell lung cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Social problem	Social circumstances	7	0.00 %
Soft tissue mass	Musculoskeletal and connective tissue disorders	7	0.00 %
Somatic symptom disorder of pregnancy	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Spinal instability	Musculoskeletal and connective tissue disorders	7	0.00 %
Splenic thrombosis	Blood and lymphatic system disorders	7	0.00 %
Splinter haemorrhages	Skin and subcutaneous tissue disorders	7	0.00 %
Streptococcal urinary tract infection	Infections and infestations	7	0.00 %
Superficial injury of eye	Injury, poisoning and procedural complications	7	0.00 %
Superior vena cava syndrome	Vascular disorders	7	0.00 %
Supraventricular tachyarrhythmia	Cardiac disorders	7	0.00 %
Sympathicotonia	Nervous system disorders	7	0.00 %
Systemic immune activation	Immune system disorders	7	0.00 %
Temperature perception test decreased	Investigations	7	0.00 %
Therapeutic product effect delayed	General disorders and administration site conditions	7	0.00 %
Therapeutic product ineffective	General disorders and administration site conditions	7	0.00 %
Therapy change	Surgical and medical procedures	7	0.00 %
Thought blocking	Psychiatric disorders	7	0.00 %
Thrombectomy	Surgical and medical procedures	7	0.00 %
Thyroglobulin increased	Investigations	7	0.00 %
Thyroxine decreased	Investigations	7	0.00 %
Tissue infiltration	General disorders and administration site conditions	7	0.00 %
Tolosa-Hunt syndrome	Eye disorders	7	0.00 %
Tonsillitis streptococcal	Infections and infestations	7	0.00 %
Tracheal oedema	Respiratory, thoracic and mediastinal disorders	7	0.00 %
Trance	Psychiatric disorders	7	0.00 %
Transferrin decreased	Investigations	7	0.00 %
Traumatic haemorrhage	Injury, poisoning and procedural complications	7	0.00 %
Treponema test positive	Investigations	7	0.00 %
Tumour pain	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7	0.00 %
Umbilical cord abnormality	Pregnancy, puerperium and perinatal conditions	7	0.00 %
Umbilical hernia	Gastrointestinal disorders	7	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Undersensing	Product issues	7	0.00 %
Urinary occult blood	Investigations	7	0.00 %
Urine leukocyte esterase positive	Investigations	7	0.00 %
Uterine haematoma	Reproductive system and breast disorders	7	0.00 %
Uterine tenderness	Reproductive system and breast disorders	7	0.00 %
Vaccination site photosensitivity reaction	General disorders and administration site conditions	7	0.00 %
Vaccination site recall reaction	General disorders and administration site conditions	7	0.00 %
Vascular graft thrombosis	Injury, poisoning and procedural complications	7	0.00 %
Vascular insufficiency	Vascular disorders	7	0.00 %
Vascular stenosis	Vascular disorders	7	0.00 %
Vasoplegia syndrome	Injury, poisoning and procedural complications	7	0.00 %
Vertebrobasilar insufficiency	Nervous system disorders	7	0.00 %
Vocal cord paresis	Nervous system disorders	7	0.00 %
Vulvovaginal rash	Reproductive system and breast disorders	7	0.00 %
Waist circumference increased	Investigations	7	0.00 %
White coat hypertension	Vascular disorders	7	0.00 %
Withdrawal hypertension	Vascular disorders	7	0.00 %
X-ray abnormal	Investigations	7	0.00 %
Acute cutaneous lupus erythematosus	Skin and subcutaneous tissue disorders	6	0.00 %
Acute haemorrhagic ulcerative colitis	Gastrointestinal disorders	6	0.00 %
Addison's disease	Endocrine disorders	6	0.00 %
Adenoma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Administration site joint movement impairment	General disorders and administration site conditions	6	0.00 %
Administration site paraesthesia	General disorders and administration site conditions	6	0.00 %
Alcohol use	Social circumstances	6	0.00 %
Allergic bronchitis	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Allergic gastroenteritis	Gastrointestinal disorders	6	0.00 %
Allergic respiratory disease	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Allergy to sting	Immune system disorders	6	0.00 %
Amputation	Surgical and medical procedures	6	0.00 %
Animal scratch	Injury, poisoning and procedural complications	6	0.00 %
Anticipatory anxiety	Psychiatric disorders	6	0.00 %
Antithrombin III deficiency	Congenital, familial and genetic disorders	6	0.00 %
Aortic embolus	Vascular disorders	6	0.00 %
Aortic valve calcification	Cardiac disorders	6	0.00 %
Aplasia pure red cell	Blood and lymphatic system disorders	6	0.00 %
Application site haematoma	General disorders and administration site conditions	6	0.00 %
Application site joint swelling	General disorders and administration site conditions	6	0.00 %
Application site oedema	General disorders and administration site conditions	6	0.00 %
Application site rash	General disorders and administration site conditions	6	0.00 %
Application site vesicles	General disorders and administration site conditions	6	0.00 %
Arterial injury	Injury, poisoning and procedural complications	6	0.00 %
Articular calcification	Musculoskeletal and connective tissue disorders	6	0.00 %
Asymptomatic bacteriuria	Infections and infestations	6	0.00 %
Atrophic vulvovaginitis	Reproductive system and breast disorders	6	0.00 %
Atypical haemolytic uraemic syndrome	Blood and lymphatic system disorders	6	0.00 %
Audiogram abnormal	Investigations	6	0.00 %
Autoimmune colitis	Gastrointestinal disorders	6	0.00 %
Autoimmune demyelinating disease	Nervous system disorders	6	0.00 %
Autoimmune uveitis	Eye disorders	6	0.00 %
Basilar migraine	Nervous system disorders	6	0.00 %
Basophil count decreased	Investigations	6	0.00 %
Birth mark	Congenital, familial and genetic disorders	6	0.00 %
Blood bicarbonate increased	Investigations	6	0.00 %
Blood bilirubin abnormal	Investigations	6	0.00 %
Blood bilirubin unconjugated increased	Investigations	6	0.00 %
Blood calcium abnormal	Investigations	6	0.00 %
Blood gases abnormal	Investigations	6	0.00 %
Blood luteinising hormone abnormal	Investigations	6	0.00 %
Blood luteinising hormone decreased	Investigations	6	0.00 %
Blood oestrogen abnormal	Investigations	6	0.00 %
Blood pH abnormal	Investigations	6	0.00 %
Blood pressure diastolic abnormal	Investigations	6	0.00 %
Blood pressure orthostatic decreased	Investigations	6	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Bone cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Bone lesion	Musculoskeletal and connective tissue disorders	6	0.00 %
Brain natriuretic peptide abnormal	Investigations	6	0.00 %
Brain stem thrombosis	Nervous system disorders	6	0.00 %
Breast milk odour abnormal	Reproductive system and breast disorders	6	0.00 %
Bronchial carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Budd-Chiari syndrome	Hepatobiliary disorders	6	0.00 %
Bursa injury	Injury, poisoning and procedural complications	6	0.00 %
Capillary permeability increased	Investigations	6	0.00 %
Cardiac function test abnormal	Investigations	6	0.00 %
Carotidynia	Vascular disorders	6	0.00 %
Cerebral cyst	Nervous system disorders	6	0.00 %
Cerebral mass effect	Nervous system disorders	6	0.00 %
Cerebral microinfarction	Nervous system disorders	6	0.00 %
Cerebral ventricle collapse	Injury, poisoning and procedural complications	6	0.00 %
Cervical discharge	Reproductive system and breast disorders	6	0.00 %
Cervical polyp	Reproductive system and breast disorders	6	0.00 %
Cervicogenic vertigo	Nervous system disorders	6	0.00 %
Cheyne-Stokes respiration	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Cholangitis acute	Hepatobiliary disorders	6	0.00 %
Cholangitis sclerosing	Hepatobiliary disorders	6	0.00 %
Chronic respiratory disease	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Colon neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Complement factor C3 increased	Investigations	6	0.00 %
Computerised tomogram thorax abnormal	Investigations	6	0.00 %
Congenital central nervous system anomaly	Congenital, familial and genetic disorders	6	0.00 %
Congenital hydrocephalus	Congenital, familial and genetic disorders	6	0.00 %
Conjunctival pallor	Eye disorders	6	0.00 %
Coombs negative haemolytic anaemia	Blood and lymphatic system disorders	6	0.00 %
Creatinine renal clearance decreased	Investigations	6	0.00 %
CSF lymphocyte count increased	Investigations	6	0.00 %
CSF red blood cell count positive	Investigations	6	0.00 %
Cystic lymphangioma	Congenital, familial and genetic disorders	6	0.00 %
Cytogenetic abnormality	Congenital, familial and genetic disorders	6	0.00 %
Dacryostenosis acquired	Eye disorders	6	0.00 %
Death neonatal	General disorders and administration site conditions	6	0.00 %
Decreased gait velocity	General disorders and administration site conditions	6	0.00 %
Decreased nasolabial fold	Musculoskeletal and connective tissue disorders	6	0.00 %
Derailment	Psychiatric disorders	6	0.00 %
Diabetic ketosis	Metabolism and nutrition disorders	6	0.00 %
Diabetic nephropathy	Renal and urinary disorders	6	0.00 %
Diaphragmatic paralysis	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Diarrhoea infectious	Infections and infestations	6	0.00 %
Dropped head syndrome	Nervous system disorders	6	0.00 %
Dry age-related macular degeneration	Eye disorders	6	0.00 %
Dural arteriovenous fistula	Nervous system disorders	6	0.00 %
Dysmorphism	Congenital, familial and genetic disorders	6	0.00 %
Dysplasia	General disorders and administration site conditions	6	0.00 %
Ejection fraction	Investigations	6	0.00 %
Electrocardiogram PR prolongation	Investigations	6	0.00 %
Electrocardiogram ST-T change	Investigations	6	0.00 %
Electromyogram abnormal	Investigations	6	0.00 %
Endocarditis bacterial	Infections and infestations	6	0.00 %
Enterobacter infection	Infections and infestations	6	0.00 %
Enzyme level increased	Investigations	6	0.00 %
Eosinophil percentage decreased	Investigations	6	0.00 %
Eosinophilic fasciitis	Musculoskeletal and connective tissue disorders	6	0.00 %
Eosinophilic myocarditis	Cardiac disorders	6	0.00 %
Ephelides	Skin and subcutaneous tissue disorders	6	0.00 %
Executive dysfunction	Psychiatric disorders	6	0.00 %
Eye infection viral	Infections and infestations	6	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Eyelash discolouration	Eye disorders	6	0.00 %
Eyelid retraction	Eye disorders	6	0.00 %
Face crushing	Injury, poisoning and procedural complications	6	0.00 %
Fallopian tube disorder	Reproductive system and breast disorders	6	0.00 %
Familial mediterranean fever	Congenital, familial and genetic disorders	6	0.00 %
Feeling guilty	Psychiatric disorders	6	0.00 %
Feelings of worthlessness	Psychiatric disorders	6	0.00 %
Female orgasmic disorder	Psychiatric disorders	6	0.00 %
Femoral artery embolism	Vascular disorders	6	0.00 %
Fibromuscular dysplasia	Vascular disorders	6	0.00 %
Fibula fracture	Injury, poisoning and procedural complications	6	0.00 %
Flashback	Psychiatric disorders	6	0.00 %
Foetal cystic hygroma	Congenital, familial and genetic disorders	6	0.00 %
Foreign body reaction	General disorders and administration site conditions	6	0.00 %
Gastroenteritis bacterial	Infections and infestations	6	0.00 %
Gastrointestinal bacterial overgrowth	Infections and infestations	6	0.00 %
Gastrointestinal mucosal disorder	Gastrointestinal disorders	6	0.00 %
Gastrointestinal ulcer	Gastrointestinal disorders	6	0.00 %
Genitourinary symptom	Renal and urinary disorders	6	0.00 %
Gianotti-Crosti syndrome	Infections and infestations	6	0.00 %
Globulins increased	Investigations	6	0.00 %
Glomerular filtration rate abnormal	Investigations	6	0.00 %
Glomerulonephritis chronic	Renal and urinary disorders	6	0.00 %
Granuloma skin	Skin and subcutaneous tissue disorders	6	0.00 %
Grief reaction	Psychiatric disorders	6	0.00 %
Haemochromatosis	Metabolism and nutrition disorders	6	0.00 %
Haemoglobin urine present	Investigations	6	0.00 %
Hallucination, tactile	Psychiatric disorders	6	0.00 %
Heat cramps	Injury, poisoning and procedural complications	6	0.00 %
Hepatic artery thrombosis	Hepatobiliary disorders	6	0.00 %
Hepatic necrosis	Hepatobiliary disorders	6	0.00 %
Hepatorenal syndrome	Hepatobiliary disorders	6	0.00 %
Herpes zoster meningoRADICULITIS	Infections and infestations	6	0.00 %
HIV test false positive	Investigations	6	0.00 %
HLA-B*27 positive	Investigations	6	0.00 %
Human chorionic gonadotropin increased	Investigations	6	0.00 %
Human herpesvirus 6 infection	Infections and infestations	6	0.00 %
Hypometabolism	Metabolism and nutrition disorders	6	0.00 %
Hypophysitis	Endocrine disorders	6	0.00 %
Hysterectomy	Surgical and medical procedures	6	0.00 %
Idiopathic angioedema	Skin and subcutaneous tissue disorders	6	0.00 %
Idiopathic inflammatory myopathy	Musculoskeletal and connective tissue disorders	6	0.00 %
Immature granulocyte count increased	Investigations	6	0.00 %
Immune-mediated encephalitis	Nervous system disorders	6	0.00 %
Inadequate aseptic technique in use of product	Injury, poisoning and procedural complications	6	0.00 %
Infected dermal cyst	Infections and infestations	6	0.00 %
Infection in an immunocompromised host	Infections and infestations	6	0.00 %
Infective glossitis	Infections and infestations	6	0.00 %
Inflammatory carcinoma of the breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Ingrowing nail	Skin and subcutaneous tissue disorders	6	0.00 %
Injection site cellulitis	Infections and infestations	6	0.00 %
Internal capsule infarction	Nervous system disorders	6	0.00 %
Intestinal mass	Gastrointestinal disorders	6	0.00 %
Intracranial haematoma	Nervous system disorders	6	0.00 %
Iris disorder	Eye disorders	6	0.00 %
Joint laxity	Musculoskeletal and connective tissue disorders	6	0.00 %
Kyphosis	Musculoskeletal and connective tissue disorders	6	0.00 %
Labia enlarged	Reproductive system and breast disorders	6	0.00 %
Lateropulsion	Nervous system disorders	6	0.00 %
Leg amputation	Surgical and medical procedures	6	0.00 %
Legionella infection	Infections and infestations	6	0.00 %
Leukoplakia	Skin and subcutaneous tissue disorders	6	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Limb crushing injury	Injury, poisoning and procedural complications	6	0.00 %
Limb malformation	Congenital, familial and genetic disorders	6	0.00 %
Liver tenderness	Hepatobiliary disorders	6	0.00 %
Locked-in syndrome	Nervous system disorders	6	0.00 %
Lordosis	Musculoskeletal and connective tissue disorders	6	0.00 %
Low density lipoprotein decreased	Investigations	6	0.00 %
Lung abscess	Infections and infestations	6	0.00 %
Lymphatic obstruction	Blood and lymphatic system disorders	6	0.00 %
Lymphorrhoea	Vascular disorders	6	0.00 %
Magnetic resonance imaging spinal abnormal	Investigations	6	0.00 %
Malaria	Infections and infestations	6	0.00 %
Mallory-Weiss syndrome	Gastrointestinal disorders	6	0.00 %
Malpositioned teeth	Gastrointestinal disorders	6	0.00 %
Mammary duct ectasia	Reproductive system and breast disorders	6	0.00 %
Mantle cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Medical diet	Surgical and medical procedures	6	0.00 %
Menopause delayed	Reproductive system and breast disorders	6	0.00 %
Mental disability	Social circumstances	6	0.00 %
Mesenteric arterial occlusion	Gastrointestinal disorders	6	0.00 %
Metatarsalgia	Musculoskeletal and connective tissue disorders	6	0.00 %
Methylenetetrahydrofolate reductase gene mutation	Congenital, familial and genetic disorders	6	0.00 %
Microalbuminuria	Renal and urinary disorders	6	0.00 %
Mitral valve stenosis	Cardiac disorders	6	0.00 %
Molluscum contagiosum	Infections and infestations	6	0.00 %
Morganella infection	Infections and infestations	6	0.00 %
Mucosal hypertrophy	General disorders and administration site conditions	6	0.00 %
Muscle enzyme increased	Investigations	6	0.00 %
Muscle hypertrophy	Musculoskeletal and connective tissue disorders	6	0.00 %
Myringitis	Infections and infestations	6	0.00 %
Nasal abscess	Infections and infestations	6	0.00 %
Necrotising myositis	Musculoskeletal and connective tissue disorders	6	0.00 %
Neonatal asphyxia	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Neonatal disorder	Pregnancy, puerperium and perinatal conditions	6	0.00 %
Non-high-density lipoprotein cholesterol increased	Investigations	6	0.00 %
Normal pressure hydrocephalus	Nervous system disorders	6	0.00 %
Norovirus infection	Infections and infestations	6	0.00 %
Nose deformity	Musculoskeletal and connective tissue disorders	6	0.00 %
Nosocomial infection	Infections and infestations	6	0.00 %
Oesophageal carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Oesophageal irritation	Gastrointestinal disorders	6	0.00 %
Omphalitis	Infections and infestations	6	0.00 %
Ophoritis	Infections and infestations	6	0.00 %
Oral mucosa haematoma	Gastrointestinal disorders	6	0.00 %
Oromandibular dystonia	Nervous system disorders	6	0.00 %
Palatal ulcer	Gastrointestinal disorders	6	0.00 %
Paralytic lagophthalmos	Eye disorders	6	0.00 %
Paranasal cyst	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Paranasal sinus haemorrhage	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Paraneoplastic syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Parkinsonian gait	Nervous system disorders	6	0.00 %
Parophthalmia	Eye disorders	6	0.00 %
Paroxysmal atrioventricular block	Cardiac disorders	6	0.00 %
Parvovirus B19 test positive	Investigations	6	0.00 %
Pathological fracture	Musculoskeletal and connective tissue disorders	6	0.00 %
Penile size reduced	Reproductive system and breast disorders	6	0.00 %
Perineal disorder	Reproductive system and breast disorders	6	0.00 %
Periorbital disorder	Eye disorders	6	0.00 %
Platelet anisocytosis	Blood and lymphatic system disorders	6	0.00 %
Platelet distribution width decreased	Investigations	6	0.00 %
Platelet morphology abnormal	Investigations	6	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Post inflammatory pigmentation change	Skin and subcutaneous tissue disorders	6	0.00 %
Posterior interosseous syndrome	Nervous system disorders	6	0.00 %
Postoperative wound infection	Infections and infestations	6	0.00 %
Primary cough headache	Nervous system disorders	6	0.00 %
Prophylaxis of nausea and vomiting	Surgical and medical procedures	6	0.00 %
Prothrombin level decreased	Investigations	6	0.00 %
Prothrombin time ratio decreased	Investigations	6	0.00 %
Pseudofolliculitis	Skin and subcutaneous tissue disorders	6	0.00 %
Pulmonary artery dilatation	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Pulmonary function test abnormal	Investigations	6	0.00 %
Pulmonary vasculitis	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Puncture site pruritus	General disorders and administration site conditions	6	0.00 %
Puncture site reaction	General disorders and administration site conditions	6	0.00 %
Recurrent cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Renal artery stenosis	Renal and urinary disorders	6	0.00 %
Renal mass	Renal and urinary disorders	6	0.00 %
Renal vascular thrombosis	Renal and urinary disorders	6	0.00 %
Respiratory tract infection bacterial	Infections and infestations	6	0.00 %
Retained placenta or membranes	Pregnancy, puerperium and perinatal conditions	6	0.00 %
Retinal aneurysm	Eye disorders	6	0.00 %
Retinal pigment epitheliopathy	Eye disorders	6	0.00 %
Retinitis pigmentosa	Congenital, familial and genetic disorders	6	0.00 %
Retinopathy hypertensive	Eye disorders	6	0.00 %
Retroperitoneal haemorrhage	Gastrointestinal disorders	6	0.00 %
Right atrial dilatation	Cardiac disorders	6	0.00 %
Saliva discolouration	Gastrointestinal disorders	6	0.00 %
Sciatic nerve palsy	Nervous system disorders	6	0.00 %
Senile dementia	Nervous system disorders	6	0.00 %
Sense of a foreshortened future	Psychiatric disorders	6	0.00 %
Silent myocardial infarction	Cardiac disorders	6	0.00 %
Skin candida	Infections and infestations	6	0.00 %
SLE arthritis	Musculoskeletal and connective tissue disorders	6	0.00 %
Slipping rib syndrome	Musculoskeletal and connective tissue disorders	6	0.00 %
Soft tissue foreign body	Injury, poisoning and procedural complications	6	0.00 %
Sperm concentration decreased	Investigations	6	0.00 %
Spina bifida	Congenital, familial and genetic disorders	6	0.00 %
Spinal cord infection	Infections and infestations	6	0.00 %
Spinal cord oedema	Nervous system disorders	6	0.00 %
Splenic cyst	Blood and lymphatic system disorders	6	0.00 %
Splenic lesion	Blood and lymphatic system disorders	6	0.00 %
Squamous cell carcinoma of skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Stoma site haemorrhage	Injury, poisoning and procedural complications	6	0.00 %
Strawberry tongue	Gastrointestinal disorders	6	0.00 %
Sympsiolysis	Musculoskeletal and connective tissue disorders	6	0.00 %
Synovial disorder	Musculoskeletal and connective tissue disorders	6	0.00 %
Syringomyelia	Congenital, familial and genetic disorders	6	0.00 %
T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Thalassaemia minor	Congenital, familial and genetic disorders	6	0.00 %
Thromboangiitis obliterans	Vascular disorders	6	0.00 %
Thyroid hormones decreased	Investigations	6	0.00 %
Tonsillar ulcer	Respiratory, thoracic and mediastinal disorders	6	0.00 %
Transferrin saturation decreased	Investigations	6	0.00 %
Tri-iodothyronine free decreased	Investigations	6	0.00 %
Troponin I abnormal	Investigations	6	0.00 %
Truncus coeliacus thrombosis	Gastrointestinal disorders	6	0.00 %
Tryptase increased	Investigations	6	0.00 %
Tumour haemorrhage	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6	0.00 %
Urethral disorder	Renal and urinary disorders	6	0.00 %
Urine albumin/creatinine ratio increased	Investigations	6	0.00 %
Urticaria physical	Skin and subcutaneous tissue disorders	6	0.00 %
Vaccination site streaking	General disorders and administration site conditions	6	0.00 %
Vaginal lesion	Reproductive system and breast disorders	6	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vascular pseudoaneurysm	Injury, poisoning and procedural complications	6	0.00 %
Ventricular failure	Cardiac disorders	6	0.00 %
Vertebral artery stenosis	Nervous system disorders	6	0.00 %
Vestibular ataxia	Ear and labyrinth disorders	6	0.00 %
Vulvovaginal ulceration	Reproductive system and breast disorders	6	0.00 %
Wound infection staphylococcal	Infections and infestations	6	0.00 %
Xanthopsia	Eye disorders	6	0.00 %
Abdominal sepsis	Infections and infestations	5	0.00 %
Abortion incomplete	Pregnancy, puerperium and perinatal conditions	5	0.00 %
Abscess bacterial	Infections and infestations	5	0.00 %
Accident at home	Injury, poisoning and procedural complications	5	0.00 %
Accident at work	Injury, poisoning and procedural complications	5	0.00 %
Acute phase reaction	General disorders and administration site conditions	5	0.00 %
ADAMTS13 activity decreased	Investigations	5	0.00 %
Adenovirus infection	Infections and infestations	5	0.00 %
Administration site rash	General disorders and administration site conditions	5	0.00 %
Adult failure to thrive	Metabolism and nutrition disorders	5	0.00 %
Agoraphobia	Psychiatric disorders	5	0.00 %
Alpha 1 globulin increased	Investigations	5	0.00 %
Alpha 2 globulin increased	Investigations	5	0.00 %
Ammonia increased	Investigations	5	0.00 %
Anal fistula	Gastrointestinal disorders	5	0.00 %
Anal hypoesthesia	Gastrointestinal disorders	5	0.00 %
Angioimmunoblastic T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Angiomyolipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Angiotensin converting enzyme decreased	Investigations	5	0.00 %
Anti-platelet antibody positive	Investigations	5	0.00 %
Antiphospholipid antibodies	Investigations	5	0.00 %
Aortic bruit	Investigations	5	0.00 %
Application site acne	General disorders and administration site conditions	5	0.00 %
Application site inflammation	General disorders and administration site conditions	5	0.00 %
Arachnoiditis	Nervous system disorders	5	0.00 %
Aspergillus infection	Infections and infestations	5	0.00 %
Atherosclerotic plaque rupture	Vascular disorders	5	0.00 %
Autoimmune dermatitis	Skin and subcutaneous tissue disorders	5	0.00 %
Autoimmune encephalopathy	Nervous system disorders	5	0.00 %
B-cell type acute leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Bacterial prostatitis	Infections and infestations	5	0.00 %
Bartholin's abscess	Infections and infestations	5	0.00 %
Bell's phenomenon	Eye disorders	5	0.00 %
Benign neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Beta globulin increased	Investigations	5	0.00 %
Beta-2 glycoprotein antibody positive	Investigations	5	0.00 %
Bile duct cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Biliary sepsis	Infections and infestations	5	0.00 %
Bilirubinuria	Renal and urinary disorders	5	0.00 %
Bladder hypertrophy	Renal and urinary disorders	5	0.00 %
Bladder obstruction	Renal and urinary disorders	5	0.00 %
Blindness cortical	Eye disorders	5	0.00 %
Block vertebra	Congenital, familial and genetic disorders	5	0.00 %
Blood albumin abnormal	Investigations	5	0.00 %
Blood folate increased	Investigations	5	0.00 %
Blood pressure normal	Investigations	5	0.00 %
Blood uric acid abnormal	Investigations	5	0.00 %
Body modification	Social circumstances	5	0.00 %
Bone density decreased	Investigations	5	0.00 %
Borderline personality disorder	Psychiatric disorders	5	0.00 %
Brachial pulse decreased	Investigations	5	0.00 %
Breast hyperplasia	Reproductive system and breast disorders	5	0.00 %
Breast injury	Injury, poisoning and procedural complications	5	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Bronchopulmonary aspergillosis	Infections and infestations	5	0.00 %
Bursitis infective	Infections and infestations	5	0.00 %
Capillary fragility increased	Investigations	5	0.00 %
Cardiac sarcoidosis	Cardiac disorders	5	0.00 %
Cardiac septal hypertrophy	Cardiac disorders	5	0.00 %
Cardiac valve vegetation	Infections and infestations	5	0.00 %
Cavernous sinus thrombosis	Infections and infestations	5	0.00 %
CD4/CD8 ratio increased	Investigations	5	0.00 %
Cellulitis orbital	Infections and infestations	5	0.00 %
Cerebellar haematoma	Nervous system disorders	5	0.00 %
Chemical burn	Injury, poisoning and procedural complications	5	0.00 %
Cholangiocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Chronic disease	General disorders and administration site conditions	5	0.00 %
Chronic idiopathic pain syndrome	Psychiatric disorders	5	0.00 %
Chronic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Clostridium test positive	Investigations	5	0.00 %
Coeliac artery stenosis	Gastrointestinal disorders	5	0.00 %
Cognitive linguistic deficit	Nervous system disorders	5	0.00 %
Cold burn	Injury, poisoning and procedural complications	5	0.00 %
Coma hepatic	Nervous system disorders	5	0.00 %
Complement factor decreased	Investigations	5	0.00 %
Complement factor increased	Investigations	5	0.00 %
Coombs positive haemolytic anaemia	Blood and lymphatic system disorders	5	0.00 %
Coronary artery bypass	Surgical and medical procedures	5	0.00 %
Coronary artery embolism	Cardiac disorders	5	0.00 %
Cough decreased	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Cross sensitivity reaction	Immune system disorders	5	0.00 %
CSF white blood cell count increased	Investigations	5	0.00 %
Cutaneous lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Dacryoadenitis acquired	Eye disorders	5	0.00 %
Decreased eye contact	Psychiatric disorders	5	0.00 %
Degenerative bone disease	Musculoskeletal and connective tissue disorders	5	0.00 %
Dependent rubor	Vascular disorders	5	0.00 %
Device malfunction	Product issues	5	0.00 %
Diabetic foot	Skin and subcutaneous tissue disorders	5	0.00 %
Diastolic hypotension	Vascular disorders	5	0.00 %
Diffusion-weighted brain MRI abnormal	Investigations	5	0.00 %
Digestive enzyme abnormal	Investigations	5	0.00 %
Drug effect less than expected	General disorders and administration site conditions	5	0.00 %
Drug effective for unapproved indication	General disorders and administration site conditions	5	0.00 %
Drug specific antibody present	Investigations	5	0.00 %
Dyssomnia	Psychiatric disorders	5	0.00 %
Eczema infantile	Skin and subcutaneous tissue disorders	5	0.00 %
Electrocardiogram ambulatory abnormal	Investigations	5	0.00 %
Encephalitis post immunisation	Nervous system disorders	5	0.00 %
Endodontic procedure	Surgical and medical procedures	5	0.00 %
Endometrial atrophy	Reproductive system and breast disorders	5	0.00 %
Enzyme abnormality	Metabolism and nutrition disorders	5	0.00 %
Epileptic encephalopathy	Nervous system disorders	5	0.00 %
Epiretinal membrane	Eye disorders	5	0.00 %
Erythropenia	Blood and lymphatic system disorders	5	0.00 %
Eye abscess	Infections and infestations	5	0.00 %
Eye lid injury	Injury, poisoning and procedural complications	5	0.00 %
Facet joint syndrome	Musculoskeletal and connective tissue disorders	5	0.00 %
Factitious disorder	Psychiatric disorders	5	0.00 %
Failure to thrive	Metabolism and nutrition disorders	5	0.00 %
Familial periodic paralysis	Congenital, familial and genetic disorders	5	0.00 %
Family stress	Social circumstances	5	0.00 %
Female sex hormone level abnormal	Investigations	5	0.00 %
Female sexual dysfunction	Reproductive system and breast disorders	5	0.00 %
Fluid intake restriction	Surgical and medical procedures	5	0.00 %
Fracture pain	Musculoskeletal and connective tissue disorders	5	0.00 %
Fulminant type 1 diabetes mellitus	Metabolism and nutrition disorders	5	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Funisitis	Infections and infestations	5	0.00 %
Gastrointestinal injury	Injury, poisoning and procedural complications	5	0.00 %
Gingival pruritus	Gastrointestinal disorders	5	0.00 %
Glossopharyngeal neuralgia	Nervous system disorders	5	0.00 %
Glycosuria	Renal and urinary disorders	5	0.00 %
Granulocytopenia	Blood and lymphatic system disorders	5	0.00 %
Gross motor delay	Nervous system disorders	5	0.00 %
Haemorrhagic urticaria	Skin and subcutaneous tissue disorders	5	0.00 %
Hand-arm vibration syndrome	Nervous system disorders	5	0.00 %
Haptoglobin increased	Investigations	5	0.00 %
Heart valve calcification	Cardiac disorders	5	0.00 %
Heparin-induced thrombocytopenia test positive	Investigations	5	0.00 %
Hepatitis A	Infections and infestations	5	0.00 %
Hepatitis B surface antibody positive	Investigations	5	0.00 %
Hereditary motor and sensory neuropathy	Congenital, familial and genetic disorders	5	0.00 %
Herpes pharyngitis	Infections and infestations	5	0.00 %
High risk pregnancy	Pregnancy, puerperium and perinatal conditions	5	0.00 %
HIV antibody positive	Investigations	5	0.00 %
Hostility	Psychiatric disorders	5	0.00 %
Hydrocholecystis	Hepatobiliary disorders	5	0.00 %
Hydrosalpinx	Reproductive system and breast disorders	5	0.00 %
Hyperactive pharyngeal reflex	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Hyperaesthesia eye	Eye disorders	5	0.00 %
Hypercreatininaemia	Metabolism and nutrition disorders	5	0.00 %
Hyperparathyroidism primary	Endocrine disorders	5	0.00 %
Hypochromasia	Blood and lymphatic system disorders	5	0.00 %
Hypoglycaemic unconsciousness	Nervous system disorders	5	0.00 %
Hypokalaemic syndrome	Metabolism and nutrition disorders	5	0.00 %
Hyponatraemic syndrome	Metabolism and nutrition disorders	5	0.00 %
Ichthyosis acquired	Skin and subcutaneous tissue disorders	5	0.00 %
Iliac artery stenosis	Vascular disorders	5	0.00 %
Immune reconstitution inflammatory syndrome	Immune system disorders	5	0.00 %
Implant site reaction	General disorders and administration site conditions	5	0.00 %
Infusion site erythema	General disorders and administration site conditions	5	0.00 %
Intervertebral disc compression	Musculoskeletal and connective tissue disorders	5	0.00 %
Intoxication by breast feeding	Injury, poisoning and procedural complications	5	0.00 %
Ischaemic limb pain	Vascular disorders	5	0.00 %
Joint destruction	Musculoskeletal and connective tissue disorders	5	0.00 %
Joint stabilisation	Surgical and medical procedures	5	0.00 %
Keratoconus	Eye disorders	5	0.00 %
Kidney congestion	Renal and urinary disorders	5	0.00 %
Klebsiella test positive	Investigations	5	0.00 %
Knee deformity	Musculoskeletal and connective tissue disorders	5	0.00 %
Koebner phenomenon	Skin and subcutaneous tissue disorders	5	0.00 %
Labour complication	Pregnancy, puerperium and perinatal conditions	5	0.00 %
Lacrimal gland enlargement	Eye disorders	5	0.00 %
Large intestinal obstruction	Gastrointestinal disorders	5	0.00 %
Left ventricular end-diastolic pressure increased	Investigations	5	0.00 %
Leukoplakia oral	Gastrointestinal disorders	5	0.00 %
Lipoatrophy	Skin and subcutaneous tissue disorders	5	0.00 %
Lung neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Luteal phase deficiency	Endocrine disorders	5	0.00 %
Lymphomatoid papulosis	Skin and subcutaneous tissue disorders	5	0.00 %
Magnetic resonance imaging heart	Investigations	5	0.00 %
Mandibular mass	Musculoskeletal and connective tissue disorders	5	0.00 %
Mastoid disorder	Ear and labyrinth disorders	5	0.00 %
Matrix metalloproteinase-3 increased	Investigations	5	0.00 %
Median nerve injury	Injury, poisoning and procedural complications	5	0.00 %
Mediastinal disorder	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Mediastinal mass	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Medical device pain	General disorders and administration site conditions	5	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Melanoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Mesenteric artery embolism	Gastrointestinal disorders	5	0.00 %
Mesenteric vascular occlusion	Gastrointestinal disorders	5	0.00 %
Metabolic alkalosis	Metabolism and nutrition disorders	5	0.00 %
Metabolic function test abnormal	Investigations	5	0.00 %
Metabolic syndrome	Metabolism and nutrition disorders	5	0.00 %
Metastatic malignant melanoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Monocytopenia	Blood and lymphatic system disorders	5	0.00 %
Mucosa vesicle	General disorders and administration site conditions	5	0.00 %
Mucosal hyperaemia	General disorders and administration site conditions	5	0.00 %
Multimorbidity	General disorders and administration site conditions	5	0.00 %
Muscle abscess	Infections and infestations	5	0.00 %
Mycoplasma infection	Infections and infestations	5	0.00 %
Myelocyte count increased	Investigations	5	0.00 %
Myocardial strain imaging abnormal	Investigations	5	0.00 %
Myoglobinuria	Renal and urinary disorders	5	0.00 %
Myxoedema	Endocrine disorders	5	0.00 %
Nail pigmentation	Skin and subcutaneous tissue disorders	5	0.00 %
Neonatal respiratory distress syndrome	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Nervous system injury	Injury, poisoning and procedural complications	5	0.00 %
Neurofibromatosis	Congenital, familial and genetic disorders	5	0.00 %
Neuropathic muscular atrophy	Musculoskeletal and connective tissue disorders	5	0.00 %
Neurosarcoidosis	Nervous system disorders	5	0.00 %
Neutropenic sepsis	Infections and infestations	5	0.00 %
Normal newborn	Pregnancy, puerperium and perinatal conditions	5	0.00 %
Obstructive shock	Vascular disorders	5	0.00 %
Ocular ischaemic syndrome	Eye disorders	5	0.00 %
Olfactory nerve disorder	Nervous system disorders	5	0.00 %
Optic disc disorder	Eye disorders	5	0.00 %
Oral mucosal scar	Injury, poisoning and procedural complications	5	0.00 %
Orbital haematoma	Eye disorders	5	0.00 %
Orbital myositis	Eye disorders	5	0.00 %
Osteochondritis	Musculoskeletal and connective tissue disorders	5	0.00 %
Otosalpingitis	Infections and infestations	5	0.00 %
Otosclerosis	Ear and labyrinth disorders	5	0.00 %
Ototoxicity	Ear and labyrinth disorders	5	0.00 %
Overwork	Social circumstances	5	0.00 %
Pain threshold decreased	Investigations	5	0.00 %
Painful ejaculation	Reproductive system and breast disorders	5	0.00 %
Pancreas infection	Infections and infestations	5	0.00 %
Pancreatic enlargement	Gastrointestinal disorders	5	0.00 %
Pancreatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Papillary thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Papulopustular rosacea	Skin and subcutaneous tissue disorders	5	0.00 %
Paradoxical embolism	Vascular disorders	5	0.00 %
Parvovirus B19 infection	Infections and infestations	5	0.00 %
Penile discharge	Reproductive system and breast disorders	5	0.00 %
Penile discomfort	Reproductive system and breast disorders	5	0.00 %
Perinatal depression	Psychiatric disorders	5	0.00 %
Peroneal nerve injury	Injury, poisoning and procedural complications	5	0.00 %
Phrenic nerve paralysis	Nervous system disorders	5	0.00 %
Pituitary apoplexy	Endocrine disorders	5	0.00 %
Placenta praevia haemorrhage	Pregnancy, puerperium and perinatal conditions	5	0.00 %
Pleural rub	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Pleurisy viral	Infections and infestations	5	0.00 %
Pneumonia fungal	Infections and infestations	5	0.00 %
Pneumonia legionella	Infections and infestations	5	0.00 %
Pneumonitis aspiration	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Poikilocytosis	Blood and lymphatic system disorders	5	0.00 %
Polychromasia	Blood and lymphatic system disorders	5	0.00 %
Polyhydramnios	Pregnancy, puerperium and perinatal conditions	5	0.00 %
Pregnancy test negative	Investigations	5	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Prehypertension	Vascular disorders	5	0.00 %
Procalcitonin decreased	Investigations	5	0.00 %
Product communication issue	Injury, poisoning and procedural complications	5	0.00 %
Progressive supranuclear palsy	Nervous system disorders	5	0.00 %
Pseudoallergic reaction	General disorders and administration site conditions	5	0.00 %
Pseudomembranous colitis	Infections and infestations	5	0.00 %
Psychotic behaviour	Psychiatric disorders	5	0.00 %
Pulmonary valve incompetence	Cardiac disorders	5	0.00 %
Pulmonary venous thrombosis	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Pyelocaliectasis	Renal and urinary disorders	5	0.00 %
Radiation associated pain	Injury, poisoning and procedural complications	5	0.00 %
Red blood cells urine	Investigations	5	0.00 %
Renal hypertrophy	Renal and urinary disorders	5	0.00 %
Renal vasculitis	Renal and urinary disorders	5	0.00 %
Respiratory rate	Investigations	5	0.00 %
Restrictive pulmonary disease	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Right ventricular enlargement	Cardiac disorders	5	0.00 %
Root canal infection	Infections and infestations	5	0.00 %
Salivary duct obstruction	Gastrointestinal disorders	5	0.00 %
Sarcopenia	Musculoskeletal and connective tissue disorders	5	0.00 %
Schwannoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Scleral disorder	Eye disorders	5	0.00 %
Seizure anoxic	Nervous system disorders	5	0.00 %
Selective eating disorder	Psychiatric disorders	5	0.00 %
Selective IgA immunodeficiency	Immune system disorders	5	0.00 %
Self-consciousness	Psychiatric disorders	5	0.00 %
Septic arthritis staphylococcal	Infections and infestations	5	0.00 %
Serotonin syndrome	Nervous system disorders	5	0.00 %
Simple partial seizures	Nervous system disorders	5	0.00 %
Skin fragility	Skin and subcutaneous tissue disorders	5	0.00 %
Skin lesion inflammation	Skin and subcutaneous tissue disorders	5	0.00 %
Spinal meningeal cyst	Nervous system disorders	5	0.00 %
Spine malformation	Congenital, familial and genetic disorders	5	0.00 %
Splenitis	Blood and lymphatic system disorders	5	0.00 %
Spondylolisthesis	Musculoskeletal and connective tissue disorders	5	0.00 %
Starvation	Metabolism and nutrition disorders	5	0.00 %
Stent-graft endoleak	General disorders and administration site conditions	5	0.00 %
Stereotypy	Psychiatric disorders	5	0.00 %
Sternal fracture	Injury, poisoning and procedural complications	5	0.00 %
Steroid diabetes	Metabolism and nutrition disorders	5	0.00 %
Subchorionic haematoma	Pregnancy, puerperium and perinatal conditions	5	0.00 %
Subglottic laryngitis	Infections and infestations	5	0.00 %
Susac's syndrome	Vascular disorders	5	0.00 %
Swollen tear duct	Eye disorders	5	0.00 %
Teeth brittle	Gastrointestinal disorders	5	0.00 %
Tetanus	Infections and infestations	5	0.00 %
Therapeutic response changed	General disorders and administration site conditions	5	0.00 %
Therapy interrupted	Surgical and medical procedures	5	0.00 %
Therapy non-responder	General disorders and administration site conditions	5	0.00 %
Thermohyperaesthesia	Nervous system disorders	5	0.00 %
Thymoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Thyroid neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %
Tinel's sign	Nervous system disorders	5	0.00 %
Tongue cyst	Gastrointestinal disorders	5	0.00 %
Tonsillar haemorrhage	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Tooth impacted	Gastrointestinal disorders	5	0.00 %
Total complement activity increased	Investigations	5	0.00 %
Toxic nodular goitre	Endocrine disorders	5	0.00 %
Transferrin increased	Investigations	5	0.00 %
Treatment failure	General disorders and administration site conditions	5	0.00 %
Tricuspid valve disease	Cardiac disorders	5	0.00 %
Triple negative breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Troponin I decreased	Investigations	5	0.00 %
Tuberculin test positive	Investigations	5	0.00 %
Tympanic membrane hyperaemia	Ear and labyrinth disorders	5	0.00 %
Type V hyperlipidaemia	Congenital, familial and genetic disorders	5	0.00 %
Uhthoff's phenomenon	Nervous system disorders	5	0.00 %
Ulna fracture	Injury, poisoning and procedural complications	5	0.00 %
Ultrasound scan abnormal	Investigations	5	0.00 %
Ureteric dilatation	Renal and urinary disorders	5	0.00 %
Urethritis noninfective	Renal and urinary disorders	5	0.00 %
Urinary sediment present	Investigations	5	0.00 %
Urticaria vesiculosa	Skin and subcutaneous tissue disorders	5	0.00 %
Vaccination site abscess sterile	General disorders and administration site conditions	5	0.00 %
Vaccination site phlebitis	General disorders and administration site conditions	5	0.00 %
Vaccine positive rechallenge	General disorders and administration site conditions	5	0.00 %
Vascular malformation	Congenital, familial and genetic disorders	5	0.00 %
Vascular stent stenosis	General disorders and administration site conditions	5	0.00 %
Vasomotor rhinitis	Respiratory, thoracic and mediastinal disorders	5	0.00 %
Ventricular tachyarrhythmia	Cardiac disorders	5	0.00 %
Vestibular function test abnormal	Investigations	5	0.00 %
Viral test positive	Investigations	5	0.00 %
Viral tonsillitis	Infections and infestations	5	0.00 %
Vitamin B12 abnormal	Investigations	5	0.00 %
Vitreous adhesions	Eye disorders	5	0.00 %
Von Willebrand's disease	Congenital, familial and genetic disorders	5	0.00 %
Wound necrosis	Injury, poisoning and procedural complications	5	0.00 %
Wrong technique in device usage process	Injury, poisoning and procedural complications	5	0.00 %
Abdominal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Abdominal wall oedema	Gastrointestinal disorders	4	0.00 %
Aborted pregnancy	Social circumstances	4	0.00 %
Abortion complete	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Acquired diaphragmatic eventration	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Acquired epidermolysis bullosa	Skin and subcutaneous tissue disorders	4	0.00 %
Acquired immunodeficiency syndrome	Infections and infestations	4	0.00 %
Activated partial thromboplastin time ratio increased	Investigations	4	0.00 %
Acute aortic syndrome	Vascular disorders	4	0.00 %
Acute chest syndrome	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Adenopathy syphilitic	Infections and infestations	4	0.00 %
Administration site joint pain	General disorders and administration site conditions	4	0.00 %
Adrenocortical steroid therapy	Surgical and medical procedures	4	0.00 %
Agraphia	Nervous system disorders	4	0.00 %
Albumin CSF increased	Investigations	4	0.00 %
Albumin globulin ratio increased	Investigations	4	0.00 %
Allergic pharyngitis	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Allergy test negative	Investigations	4	0.00 %
Allergy test positive	Investigations	4	0.00 %
Alpha globulin increased	Investigations	4	0.00 %
Alveolar lung disease	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Amoebiasis	Infections and infestations	4	0.00 %
Anaemia folate deficiency	Blood and lymphatic system disorders	4	0.00 %
Anal inflammation	Gastrointestinal disorders	4	0.00 %
Anal rash	Gastrointestinal disorders	4	0.00 %
Anal ulcer	Gastrointestinal disorders	4	0.00 %
Analgesic drug level	Investigations	4	0.00 %
Angiogram pulmonary abnormal	Investigations	4	0.00 %
Anorectal swelling	Gastrointestinal disorders	4	0.00 %
Anti-ganglioside antibody positive	Investigations	4	0.00 %
Anti-glomerular basement membrane disease	Renal and urinary disorders	4	0.00 %
Anti-IA2 antibody positive	Investigations	4	0.00 %
Anticoagulant therapy	Surgical and medical procedures	4	0.00 %
Aortic elongation	Vascular disorders	4	0.00 %
Aortic intramural haematoma	Vascular disorders	4	0.00 %
Application site paraesthesia	General disorders and administration site conditions	4	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Arrhythmic storm	Cardiac disorders	4	0.00 %
Arrhythmogenic right ventricular dysplasia	Congenital, familial and genetic disorders	4	0.00 %
Arterial spasm	Vascular disorders	4	0.00 %
Arthrodesis	Surgical and medical procedures	4	0.00 %
AST/ALT ratio abnormal	Investigations	4	0.00 %
Atrioventricular septal defect	Congenital, familial and genetic disorders	4	0.00 %
Atrophic glossitis	Gastrointestinal disorders	4	0.00 %
Autoimmune blistering disease	Skin and subcutaneous tissue disorders	4	0.00 %
Autoimmune myocarditis	Cardiac disorders	4	0.00 %
Autonomic seizure	Nervous system disorders	4	0.00 %
Autophony	Ear and labyrinth disorders	4	0.00 %
Bacterial diarrhoea	Infections and infestations	4	0.00 %
Band neutrophil percentage increased	Investigations	4	0.00 %
Base excess decreased	Investigations	4	0.00 %
Basilar artery stenosis	Nervous system disorders	4	0.00 %
Benign lymph node neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Bicuspid aortic valve	Congenital, familial and genetic disorders	4	0.00 %
Bilirubin urine present	Investigations	4	0.00 %
Bladder cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Bladder injury	Injury, poisoning and procedural complications	4	0.00 %
Bladder neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Blood alcohol increased	Investigations	4	0.00 %
Blood brain barrier defect	Nervous system disorders	4	0.00 %
Blood glucose	Investigations	4	0.00 %
Blood glucose normal	Investigations	4	0.00 %
Blood ketone body	Investigations	4	0.00 %
Blood lactic acid abnormal	Investigations	4	0.00 %
Blood lactic acid decreased	Investigations	4	0.00 %
Blood pressure ambulatory abnormal	Investigations	4	0.00 %
Blood pressure orthostatic abnormal	Investigations	4	0.00 %
Blood triglycerides decreased	Investigations	4	0.00 %
Blood viscosity abnormal	Investigations	4	0.00 %
Bone cyst	Musculoskeletal and connective tissue disorders	4	0.00 %
Bone deformity	Musculoskeletal and connective tissue disorders	4	0.00 %
Bone fissure	Injury, poisoning and procedural complications	4	0.00 %
Bone loss	Musculoskeletal and connective tissue disorders	4	0.00 %
Boredom	Psychiatric disorders	4	0.00 %
Breast cancer male	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Breast prosthesis user	Social circumstances	4	0.00 %
Breathing-related sleep disorder	Psychiatric disorders	4	0.00 %
Bronchial oedema	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Brow ptosis	Skin and subcutaneous tissue disorders	4	0.00 %
Bullous impetigo	Infections and infestations	4	0.00 %
Buttock injury	Injury, poisoning and procedural complications	4	0.00 %
Calcium ionised decreased	Investigations	4	0.00 %
Carbohydrate antigen 19-9 increased	Investigations	4	0.00 %
Cardiac cirrhosis	Hepatobiliary disorders	4	0.00 %
Cardiac procedure complication	Injury, poisoning and procedural complications	4	0.00 %
Cardiovascular deconditioning	Cardiac disorders	4	0.00 %
Cardiovascular somatic symptom disorder	Psychiatric disorders	4	0.00 %
Carotid bruit	Investigations	4	0.00 %
Carotid pulse	Investigations	4	0.00 %
Cataract nuclear	Eye disorders	4	0.00 %
Catheter site pain	General disorders and administration site conditions	4	0.00 %
Cellulitis staphylococcal	Infections and infestations	4	0.00 %
Cerebral haemorrhage foetal	Nervous system disorders	4	0.00 %
Cerebral hypoperfusion	Nervous system disorders	4	0.00 %
Cerebrospinal fluid circulation disorder	Nervous system disorders	4	0.00 %
Cerebrovascular arteriovenous malformation	Congenital, familial and genetic disorders	4	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Cervical incompetence	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Chest X-ray normal	Investigations	4	0.00 %
Chlamydia test positive	Investigations	4	0.00 %
Chordae tendinae rupture	Cardiac disorders	4	0.00 %
Choroidal effusion	Eye disorders	4	0.00 %
Chronic inflammatory response syndrome	General disorders and administration site conditions	4	0.00 %
Chronic tonsillitis	Infections and infestations	4	0.00 %
Cleft lip and palate	Congenital, familial and genetic disorders	4	0.00 %
Coccidioidomycosis	Infections and infestations	4	0.00 %
Cogwheel rigidity	Nervous system disorders	4	0.00 %
Complement factor C4 decreased	Investigations	4	0.00 %
Computerised tomogram head abnormal	Investigations	4	0.00 %
Convulsive threshold lowered	Nervous system disorders	4	0.00 %
Corneal lesion	Eye disorders	4	0.00 %
Coronary artery aneurysm	Cardiac disorders	4	0.00 %
Coronary ostial stenosis	Cardiac disorders	4	0.00 %
Coxsackie virus test positive	Investigations	4	0.00 %
Cranial nerve injury	Injury, poisoning and procedural complications	4	0.00 %
Craniofacial injury	Injury, poisoning and procedural complications	4	0.00 %
Critical illness	General disorders and administration site conditions	4	0.00 %
CSF myelin basic protein increased	Investigations	4	0.00 %
Cushing's syndrome	Endocrine disorders	4	0.00 %
Cyclic vomiting syndrome	Gastrointestinal disorders	4	0.00 %
Cytokine increased	Investigations	4	0.00 %
Cytotoxic oedema	Nervous system disorders	4	0.00 %
Dacryocystitis	Infections and infestations	4	0.00 %
Deafness traumatic	Injury, poisoning and procedural complications	4	0.00 %
Deformity thorax	Musculoskeletal and connective tissue disorders	4	0.00 %
Delayed recovery from anaesthesia	Injury, poisoning and procedural complications	4	0.00 %
Delusional disorder, unspecified type	Psychiatric disorders	4	0.00 %
Dental cyst	Gastrointestinal disorders	4	0.00 %
Dermatophytosis	Infections and infestations	4	0.00 %
Device dislocation	Product issues	4	0.00 %
Diaphragmatic hernia	Gastrointestinal disorders	4	0.00 %
Disease complication	General disorders and administration site conditions	4	0.00 %
Diverticulitis intestinal haemorrhagic	Infections and infestations	4	0.00 %
Drooping shoulder syndrome	Musculoskeletal and connective tissue disorders	4	0.00 %
Drug screen positive	Investigations	4	0.00 %
Ear infection fungal	Infections and infestations	4	0.00 %
Ear, nose and throat examination abnormal	Investigations	4	0.00 %
Ear, nose and throat infection	Infections and infestations	4	0.00 %
Ectropion	Eye disorders	4	0.00 %
Electrocardiogram low voltage	Investigations	4	0.00 %
Electrocardiogram QRS complex abnormal	Investigations	4	0.00 %
Electrocardiogram T wave amplitude decreased	Investigations	4	0.00 %
Electrophoresis abnormal	Investigations	4	0.00 %
Embolic cerebellar infarction	Nervous system disorders	4	0.00 %
Eosinophilic pneumonia acute	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Epididymal cyst	Reproductive system and breast disorders	4	0.00 %
Epinephrine abnormal	Investigations	4	0.00 %
Escherichia pyelonephritis	Infections and infestations	4	0.00 %
Exaggerated startle response	Nervous system disorders	4	0.00 %
Exercise tolerance increased	General disorders and administration site conditions	4	0.00 %
Exposure to toxic agent	Injury, poisoning and procedural complications	4	0.00 %
External ear cellulitis	Infections and infestations	4	0.00 %
External ear disorder	Ear and labyrinth disorders	4	0.00 %
Eye naevus	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Eye operation	Surgical and medical procedures	4	0.00 %
Eyelid vascular disorder	Eye disorders	4	0.00 %
Facial myokymia	Musculoskeletal and connective tissue disorders	4	0.00 %
Factor II mutation	Congenital, familial and genetic disorders	4	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Factor V deficiency	Congenital, familial and genetic disorders	4	0.00 %
Faecal volume decreased	Investigations	4	0.00 %
Fallot's tetralogy	Congenital, familial and genetic disorders	4	0.00 %
Fear of eating	Psychiatric disorders	4	0.00 %
Fear-related avoidance of activities	Psychiatric disorders	4	0.00 %
Fibrous histiocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Focal peritonitis	Infections and infestations	4	0.00 %
Foetal chromosome abnormality	Congenital, familial and genetic disorders	4	0.00 %
Foetal disorder	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Food interaction	General disorders and administration site conditions	4	0.00 %
Foreign body aspiration	Injury, poisoning and procedural complications	4	0.00 %
Fuchs' syndrome	Eye disorders	4	0.00 %
Full blood count	Investigations	4	0.00 %
Gait spastic	Nervous system disorders	4	0.00 %
Gastric perforation	Gastrointestinal disorders	4	0.00 %
Gastritis haemorrhagic	Gastrointestinal disorders	4	0.00 %
Gastrointestinal stoma complication	Injury, poisoning and procedural complications	4	0.00 %
Gastroschisis	Congenital, familial and genetic disorders	4	0.00 %
Generalised onset non-motor seizure	Nervous system disorders	4	0.00 %
Genital infection female	Infections and infestations	4	0.00 %
Genito-pelvic pain/penetration disorder	Psychiatric disorders	4	0.00 %
Glomerulonephritis	Renal and urinary disorders	4	0.00 %
membranoproliferative			
Glucose-6-phosphate dehydrogenase deficiency	Congenital, familial and genetic disorders	4	0.00 %
Glycogen storage disease type V	Congenital, familial and genetic disorders	4	0.00 %
Glycosylated haemoglobin abnormal	Investigations	4	0.00 %
Haemophilus infection	Infections and infestations	4	0.00 %
Head deformity	Musculoskeletal and connective tissue disorders	4	0.00 %
Hemiparesia	Nervous system disorders	4	0.00 %
Hepatitis A antibody positive	Investigations	4	0.00 %
Hereditary haemorrhagic telangiectasia	Congenital, familial and genetic disorders	4	0.00 %
Hernia repair	Surgical and medical procedures	4	0.00 %
Herpangina	Infections and infestations	4	0.00 %
High-pitched crying	General disorders and administration site conditions	4	0.00 %
Histiocytosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Homans' sign positive	Investigations	4	0.00 %
Homonymous diplopia	Eye disorders	4	0.00 %
Human chorionic gonadotropin decreased	Investigations	4	0.00 %
Human papilloma virus test positive	Investigations	4	0.00 %
Hyperammonaemia	Metabolism and nutrition disorders	4	0.00 %
Hypercapnic coma	Nervous system disorders	4	0.00 %
Hypergammaglobulinaemia benign monoclonal	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Hyperprolactinaemia	Endocrine disorders	4	0.00 %
Hypersensitivity myocarditis	Cardiac disorders	4	0.00 %
Hyperthermia malignant	General disorders and administration site conditions	4	0.00 %
Hyphaema	Injury, poisoning and procedural complications	4	0.00 %
Hypoferritinaemia	Metabolism and nutrition disorders	4	0.00 %
Hypoglycaemia neonatal	Metabolism and nutrition disorders	4	0.00 %
Hypoglycaemic coma	Nervous system disorders	4	0.00 %
Hypoplastic left heart syndrome	Congenital, familial and genetic disorders	4	0.00 %
Idiopathic orbital inflammation	Eye disorders	4	0.00 %
Illiteracy	Social circumstances	4	0.00 %
Immune-mediated neurological disorder	Nervous system disorders	4	0.00 %
Immunoglobulins abnormal	Investigations	4	0.00 %
Immunology test	Investigations	4	0.00 %
Impaired ability to use machinery	Social circumstances	4	0.00 %
Implant site erythema	General disorders and administration site conditions	4	0.00 %
Implant site extravasation	General disorders and administration site conditions	4	0.00 %
Implant site inflammation	General disorders and administration site conditions	4	0.00 %
Implant site oedema	General disorders and administration site conditions	4	0.00 %
Implant site warmth	General disorders and administration site conditions	4	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Impulsive behaviour	Psychiatric disorders	4	0.00 %
Incision site swelling	Injury, poisoning and procedural complications	4	0.00 %
Infective pericardial effusion	Infections and infestations	4	0.00 %
Inferior vena caval occlusion	Vascular disorders	4	0.00 %
Infusion related hypersensitivity reaction	Immune system disorders	4	0.00 %
Infusion site joint swelling	General disorders and administration site conditions	4	0.00 %
Infusion site pruritus	General disorders and administration site conditions	4	0.00 %
Injection site irritation	General disorders and administration site conditions	4	0.00 %
Injection site joint swelling	General disorders and administration site conditions	4	0.00 %
Injection site muscle atrophy	General disorders and administration site conditions	4	0.00 %
Insulin C-peptide decreased	Investigations	4	0.00 %
Intercepted medication error	Injury, poisoning and procedural complications	4	0.00 %
Interferon gamma release assay positive	Investigations	4	0.00 %
Intervertebral disc annular tear	Musculoskeletal and connective tissue disorders	4	0.00 %
Intestinal angioedema	Gastrointestinal disorders	4	0.00 %
Intestinal pseudo-obstruction	Gastrointestinal disorders	4	0.00 %
Intestinal stenosis	Gastrointestinal disorders	4	0.00 %
Intestinal transit time decreased	Investigations	4	0.00 %
Intrapartum haemorrhage	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Intrauterine infection	Infections and infestations	4	0.00 %
Iron overload	Metabolism and nutrition disorders	4	0.00 %
IVth nerve disorder	Nervous system disorders	4	0.00 %
Jaw cyst	Musculoskeletal and connective tissue disorders	4	0.00 %
Joint injection	Surgical and medical procedures	4	0.00 %
Keratic precipitates	Eye disorders	4	0.00 %
Keratouveitis	Infections and infestations	4	0.00 %
Ketonuria	Renal and urinary disorders	4	0.00 %
Kidney malformation	Congenital, familial and genetic disorders	4	0.00 %
Knee operation	Surgical and medical procedures	4	0.00 %
Labour induction	Surgical and medical procedures	4	0.00 %
Lack of vaccination site rotation	Injury, poisoning and procedural complications	4	0.00 %
Langerhans' cell histiocytosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Learning disorder	Psychiatric disorders	4	0.00 %
Leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Lichen striatus	Skin and subcutaneous tissue disorders	4	0.00 %
Limbal swelling	Eye disorders	4	0.00 %
Lip and/or oral cavity cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Long QT syndrome	Cardiac disorders	4	0.00 %
Low density lipoprotein abnormal	Investigations	4	0.00 %
Lumbar puncture abnormal	Investigations	4	0.00 %
Lymph node haemorrhage	Blood and lymphatic system disorders	4	0.00 %
Lymphadenitis bacterial	Infections and infestations	4	0.00 %
Lymphangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Lymphocyte count	Investigations	4	0.00 %
Macroangiopathy	Vascular disorders	4	0.00 %
Macular detachment	Eye disorders	4	0.00 %
Magnetic resonance imaging	Investigations	4	0.00 %
Malignant ascites	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Malignant peritoneal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Maximum heart rate increased	Investigations	4	0.00 %
Medical device monitoring error	Injury, poisoning and procedural complications	4	0.00 %
Melkersson-Rosenthal syndrome	Congenital, familial and genetic disorders	4	0.00 %
Mesenteric artery stenosis	Gastrointestinal disorders	4	0.00 %
Metamyelocyte count increased	Investigations	4	0.00 %
Metastases to peritoneum	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Micropenis	Congenital, familial and genetic disorders	4	0.00 %
Middle East respiratory syndrome	Infections and infestations	4	0.00 %
Migraine-triggered seizure	Nervous system disorders	4	0.00 %
Milia	Skin and subcutaneous tissue disorders	4	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Mineral supplementation	Surgical and medical procedures	4	0.00 %
Mitral valve sclerosis	Cardiac disorders	4	0.00 %
Mixed deafness	Ear and labyrinth disorders	4	0.00 %
Mononuclear cell count increased	Investigations	4	0.00 %
Mucosal discolouration	General disorders and administration site conditions	4	0.00 %
Multifocal motor neuropathy	Nervous system disorders	4	0.00 %
Multiple use of single-use product	Injury, poisoning and procedural complications	4	0.00 %
Musculoskeletal injury	Injury, poisoning and procedural complications	4	0.00 %
Myelocytosis	Blood and lymphatic system disorders	4	0.00 %
Myelofibrosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Myeloid leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Myocarditis septic	Infections and infestations	4	0.00 %
Nail bed disorder	Skin and subcutaneous tissue disorders	4	0.00 %
Nail discomfort	Skin and subcutaneous tissue disorders	4	0.00 %
Nail infection	Infections and infestations	4	0.00 %
Nail injury	Injury, poisoning and procedural complications	4	0.00 %
Necrotising colitis	Gastrointestinal disorders	4	0.00 %
Neoplasm swelling	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Neuroendocrine tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Neurological eyelid disorder	Eye disorders	4	0.00 %
Neuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Neuromuscular blockade	Nervous system disorders	4	0.00 %
Nipple infection	Infections and infestations	4	0.00 %
Nodal arrhythmia	Cardiac disorders	4	0.00 %
Non-tobacco user	Social circumstances	4	0.00 %
Noninfective myringitis	Ear and labyrinth disorders	4	0.00 %
Oedema blister	Skin and subcutaneous tissue disorders	4	0.00 %
Oedema due to cardiac disease	General disorders and administration site conditions	4	0.00 %
Oesophageal haemorrhage	Gastrointestinal disorders	4	0.00 %
Oesophageal perforation	Gastrointestinal disorders	4	0.00 %
Oesophageal rupture	Gastrointestinal disorders	4	0.00 %
On and off phenomenon	Nervous system disorders	4	0.00 %
Open angle glaucoma	Eye disorders	4	0.00 %
Ophthalmic artery occlusion	Eye disorders	4	0.00 %
Oral administration complication	General disorders and administration site conditions	4	0.00 %
Oral lichenoid reaction	Gastrointestinal disorders	4	0.00 %
Oral purpura	Gastrointestinal disorders	4	0.00 %
Oral viral infection	Infections and infestations	4	0.00 %
Orbital cyst	Eye disorders	4	0.00 %
Orgasm abnormal	Psychiatric disorders	4	0.00 %
Osteochondrosis	Musculoskeletal and connective tissue disorders	4	0.00 %
Osteolysis	Musculoskeletal and connective tissue disorders	4	0.00 %
Osteonecrosis of jaw	Musculoskeletal and connective tissue disorders	4	0.00 %
Osteoporotic fracture	Musculoskeletal and connective tissue disorders	4	0.00 %
Ovarian mass	Reproductive system and breast disorders	4	0.00 %
Oxygen consumption increased	Investigations	4	0.00 %
Paget-Schroetter syndrome	Vascular disorders	4	0.00 %
Palliative care	Surgical and medical procedures	4	0.00 %
Pancreatic carcinoma metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Pancreatitis relapsing	Gastrointestinal disorders	4	0.00 %
Paradoxical drug reaction	General disorders and administration site conditions	4	0.00 %
Parkinsonian rest tremor	Nervous system disorders	4	0.00 %
Paroxysmal extreme pain disorder	Congenital, familial and genetic disorders	4	0.00 %
Partner stress	Social circumstances	4	0.00 %
Patellofemoral pain syndrome	Musculoskeletal and connective tissue disorders	4	0.00 %
Pathergy reaction	Skin and subcutaneous tissue disorders	4	0.00 %
Pelvic congestion	Reproductive system and breast disorders	4	0.00 %
Pelvic floor dysfunction	Gastrointestinal disorders	4	0.00 %
Pelvic fluid collection	Reproductive system and breast disorders	4	0.00 %
Penile exfoliation	Reproductive system and breast disorders	4	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Penile haematoma	Reproductive system and breast disorders	4	0.00 %
Penile ulceration	Skin and subcutaneous tissue disorders	4	0.00 %
Periodontal disease	Gastrointestinal disorders	4	0.00 %
Peripartum haemorrhage	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Peripheral pulse decreased	Investigations	4	0.00 %
Peritonitis bacterial	Infections and infestations	4	0.00 %
Persistent genital arousal disorder	Nervous system disorders	4	0.00 %
pH urine	Investigations	4	0.00 %
Phaeochromocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Phimosis	Congenital, familial and genetic disorders	4	0.00 %
Photodermatosis	Skin and subcutaneous tissue disorders	4	0.00 %
Pineal gland cyst	Nervous system disorders	4	0.00 %
Placental infarction	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Plasma cell myeloma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Plasmacytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Platelet aggregation abnormal	Investigations	4	0.00 %
Platelet aggregation increased	Investigations	4	0.00 %
Pneumatosis	General disorders and administration site conditions	4	0.00 %
Pneumonia chlamydial	Infections and infestations	4	0.00 %
Pneumoperitoneum	Gastrointestinal disorders	4	0.00 %
POEMS syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Polymerase chain reaction	Investigations	4	0.00 %
Polyneuropathy chronic	Nervous system disorders	4	0.00 %
Porphyria	Congenital, familial and genetic disorders	4	0.00 %
Porphyria acute	Congenital, familial and genetic disorders	4	0.00 %
Portal vein occlusion	Hepatobiliary disorders	4	0.00 %
Positron emission tomogram abnormal	Investigations	4	0.00 %
Post procedural inflammation	Injury, poisoning and procedural complications	4	0.00 %
Post-tussive vomiting	Gastrointestinal disorders	4	0.00 %
Postoperative delirium	Injury, poisoning and procedural complications	4	0.00 %
Postprandial hypoglycaemia	Metabolism and nutrition disorders	4	0.00 %
Postural tremor	Nervous system disorders	4	0.00 %
Pregnancy after post coital contraception	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Premature baby death	General disorders and administration site conditions	4	0.00 %
Pressure of speech	Psychiatric disorders	4	0.00 %
Primary hyperthyroidism	Endocrine disorders	4	0.00 %
Prion disease	Infections and infestations	4	0.00 %
Product formulation issue	Product issues	4	0.00 %
Product impurity	Product issues	4	0.00 %
Product intolerance	General disorders and administration site conditions	4	0.00 %
Product residue present	Investigations	4	0.00 %
Prolonged labour	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Protein S decreased	Investigations	4	0.00 %
Protein S deficiency	Congenital, familial and genetic disorders	4	0.00 %
Pseudocyst	General disorders and administration site conditions	4	0.00 %
Psychological factor affecting medical condition	Psychiatric disorders	4	0.00 %
Pterygium	Eye disorders	4	0.00 %
Pulmonary artery occlusion	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Pulmonary calcification	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Pulmonary hypoperfusion	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Pulmonary sensitisation	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Pulmonary valve stenosis	Cardiac disorders	4	0.00 %
Puncture site haemorrhage	General disorders and administration site conditions	4	0.00 %
Pupillary light reflex tests abnormal	Investigations	4	0.00 %
Purpura senile	Skin and subcutaneous tissue disorders	4	0.00 %
Pyoderma	Infections and infestations	4	0.00 %
Pyogenic granuloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Radial pulse decreased	Investigations	4	0.00 %
Rash neonatal	Skin and subcutaneous tissue disorders	4	0.00 %
Reactive gastropathy	Injury, poisoning and procedural complications	4	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Rectal ulcer	Gastrointestinal disorders	4	0.00 %
Refraction disorder	Eye disorders	4	0.00 %
Refusal of treatment by patient	Social circumstances	4	0.00 %
Respiratory gas exchange disorder	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Respiratory paralysis	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Reticulocytosis	Blood and lymphatic system disorders	4	0.00 %
Retirement	Social circumstances	4	0.00 %
Reversible airways obstruction	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Reversible splenial lesion syndrome	Nervous system disorders	4	0.00 %
Reynold's syndrome	Musculoskeletal and connective tissue disorders	4	0.00 %
Saccadic eye movement	Eye disorders	4	0.00 %
Salivary gland calculus	Gastrointestinal disorders	4	0.00 %
Salivary gland mass	Gastrointestinal disorders	4	0.00 %
SAPHO syndrome	Musculoskeletal and connective tissue disorders	4	0.00 %
SARS-CoV-1 test positive	Investigations	4	0.00 %
Scleral cyst	Eye disorders	4	0.00 %
Scleral hyperaemia	Eye disorders	4	0.00 %
Scrotal discomfort	Reproductive system and breast disorders	4	0.00 %
Second primary malignancy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Secondary adrenocortical insufficiency	Endocrine disorders	4	0.00 %
Secondary transmission	Infections and infestations	4	0.00 %
Sensory level	Investigations	4	0.00 %
Septic rash	Infections and infestations	4	0.00 %
Seroconversion test negative	Investigations	4	0.00 %
Serous retinal detachment	Eye disorders	4	0.00 %
Shortened cervix	Reproductive system and breast disorders	4	0.00 %
Sick relative	Social circumstances	4	0.00 %
Single umbilical artery	Congenital, familial and genetic disorders	4	0.00 %
Sinus polyp	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Skin turgor decreased	Investigations	4	0.00 %
Sleep inertia	Psychiatric disorders	4	0.00 %
Small intestinal perforation	Gastrointestinal disorders	4	0.00 %
Smallpox	Infections and infestations	4	0.00 %
Smooth muscle antibody positive	Investigations	4	0.00 %
Soft tissue haemorrhage	Musculoskeletal and connective tissue disorders	4	0.00 %
Spasmodic dysphonia	Nervous system disorders	4	0.00 %
Specific gravity urine decreased	Investigations	4	0.00 %
Spermatozoa abnormal	Investigations	4	0.00 %
Spider naevus	Skin and subcutaneous tissue disorders	4	0.00 %
Spinal cord haemorrhage	Nervous system disorders	4	0.00 %
Stab wound	Injury, poisoning and procedural complications	4	0.00 %
Sternitis	Infections and infestations	4	0.00 %
Streptobacillus infection	Infections and infestations	4	0.00 %
Subdural hygroma	Nervous system disorders	4	0.00 %
Subretinal fluid	Eye disorders	4	0.00 %
Substance use	Social circumstances	4	0.00 %
Suicide threat	Psychiatric disorders	4	0.00 %
Superovulation	Reproductive system and breast disorders	4	0.00 %
Supine position	Surgical and medical procedures	4	0.00 %
Sweat discolouration	Skin and subcutaneous tissue disorders	4	0.00 %
Syndactyly	Congenital, familial and genetic disorders	4	0.00 %
Synkinesis	Nervous system disorders	4	0.00 %
Systemic infection	Infections and infestations	4	0.00 %
T-lymphocyte count decreased	Investigations	4	0.00 %
Tachycardia induced cardiomyopathy	Cardiac disorders	4	0.00 %
Testicular oedema	Reproductive system and breast disorders	4	0.00 %
Therapeutic procedure	Surgical and medical procedures	4	0.00 %
Thoracic haemorrhage	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Thymus enlargement	Blood and lymphatic system disorders	4	0.00 %
Thyroglossal cyst	Congenital, familial and genetic disorders	4	0.00 %
Thyroid adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0.00 %
Tobacco user	Social circumstances	4	0.00 %
Tonic posturing	Nervous system disorders	4	0.00 %
Tooth avulsion	Injury, poisoning and procedural complications	4	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Total lung capacity abnormal	Investigations	4	0.00 %
Tracheobronchitis	Infections and infestations	4	0.00 %
Tracheobronchitis bacterial	Infections and infestations	4	0.00 %
Transaminases abnormal	Investigations	4	0.00 %
Trifascicular block	Cardiac disorders	4	0.00 %
Troponin I	Investigations	4	0.00 %
Tumour marker decreased	Investigations	4	0.00 %
Type II hypersensitivity	Immune system disorders	4	0.00 %
Ulnar tunnel syndrome	Nervous system disorders	4	0.00 %
Umbilical cord thrombosis	Pregnancy, puerperium and perinatal conditions	4	0.00 %
Upper motor neurone lesion	Nervous system disorders	4	0.00 %
Urinary tract infection enterococcal	Infections and infestations	4	0.00 %
Urinary tract infection fungal	Infections and infestations	4	0.00 %
Urine copper	Investigations	4	0.00 %
Urticaria contact	Skin and subcutaneous tissue disorders	4	0.00 %
Uterine prolapse	Reproductive system and breast disorders	4	0.00 %
Vaccination site calcification	General disorders and administration site conditions	4	0.00 %
Vaccination site joint effusion	General disorders and administration site conditions	4	0.00 %
Vaccine associated enhanced respiratory disease	Immune system disorders	4	0.00 %
Vaginal abscess	Infections and infestations	4	0.00 %
Vaginal mucosal blistering	Reproductive system and breast disorders	4	0.00 %
Vaginitis gardnerella	Infections and infestations	4	0.00 %
Vagus nerve paralysis	Nervous system disorders	4	0.00 %
Varicose ulceration	Vascular disorders	4	0.00 %
Varicose veins vulval	Reproductive system and breast disorders	4	0.00 %
Vascular compression	Vascular disorders	4	0.00 %
Vascular device infection	Infections and infestations	4	0.00 %
Vascular fragility	Vascular disorders	4	0.00 %
Vascular graft occlusion	Injury, poisoning and procedural complications	4	0.00 %
Vascular skin disorder	Skin and subcutaneous tissue disorders	4	0.00 %
Vasogenic cerebral oedema	Nervous system disorders	4	0.00 %
Venous angioma of brain	Congenital, familial and genetic disorders	4	0.00 %
Venous pressure jugular increased	Investigations	4	0.00 %
Venous stasis retinopathy	Eye disorders	4	0.00 %
Ventricle rupture	Cardiac disorders	4	0.00 %
Ventricular dyskinesia	Cardiac disorders	4	0.00 %
Ventricular flutter	Cardiac disorders	4	0.00 %
Vertebral foraminal stenosis	Musculoskeletal and connective tissue disorders	4	0.00 %
Vertebral lesion	Musculoskeletal and connective tissue disorders	4	0.00 %
Vessel puncture site haematoma	General disorders and administration site conditions	4	0.00 %
Vessel puncture site injury	General disorders and administration site conditions	4	0.00 %
VIIIth nerve lesion	Nervous system disorders	4	0.00 %
Viral diarrhoea	Infections and infestations	4	0.00 %
Visuospatial deficit	Nervous system disorders	4	0.00 %
Vitamin B complex deficiency	Metabolism and nutrition disorders	4	0.00 %
Vitamin B6 increased	Investigations	4	0.00 %
Vitamin C deficiency	Metabolism and nutrition disorders	4	0.00 %
Vitreous degeneration	Eye disorders	4	0.00 %
Vitritis	Eye disorders	4	0.00 %
Vocal cord thickening	Respiratory, thoracic and mediastinal disorders	4	0.00 %
Von Willebrand's factor activity increased	Investigations	4	0.00 %
Vulval abscess	Infections and infestations	4	0.00 %
Vulvovaginitis	Infections and infestations	4	0.00 %
Weight gain poor	Metabolism and nutrition disorders	4	0.00 %
White blood cell count	Investigations	4	0.00 %
Yersinia infection	Infections and infestations	4	0.00 %
Abdominal injury	Injury, poisoning and procedural complications	3	0.00 %
Abdominal migraine	Gastrointestinal disorders	3	0.00 %
Abdominal operation	Surgical and medical procedures	3	0.00 %
Abdominal wall haemorrhage	Gastrointestinal disorders	3	0.00 %
Aberrant motor behaviour	Psychiatric disorders	3	0.00 %
Abnormal labour	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Abortion of ectopic pregnancy	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Abscess jaw	Infections and infestations	3	0.00 %
Abscess of eyelid	Infections and infestations	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Abscess of salivary gland	Infections and infestations	3	0.00 %
Accessory muscle	Congenital, familial and genetic disorders	3	0.00 %
Accessory spleen	Congenital, familial and genetic disorders	3	0.00 %
Accidental exposure to product by child	Injury, poisoning and procedural complications	3	0.00 %
Acid base balance abnormal	Investigations	3	0.00 %
Acne conglobata	Skin and subcutaneous tissue disorders	3	0.00 %
Acquired Von Willebrand's disease	Blood and lymphatic system disorders	3	0.00 %
Activated partial thromboplastin time abnormal	Investigations	3	0.00 %
Acute flaccid myelitis	Nervous system disorders	3	0.00 %
Acute lung injury	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Adams-Stokes syndrome	Cardiac disorders	3	0.00 %
Adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Adenocarcinoma of colon	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Adenosine deaminase increased	Investigations	3	0.00 %
Adenoviral conjunctivitis	Infections and infestations	3	0.00 %
Administration site discomfort	General disorders and administration site conditions	3	0.00 %
Administration site extravasation	General disorders and administration site conditions	3	0.00 %
Administration site haematoma	General disorders and administration site conditions	3	0.00 %
Administration site warmth	General disorders and administration site conditions	3	0.00 %
Adrenal gland cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Aerococcus urinae infection	Infections and infestations	3	0.00 %
Agitation neonatal	Nervous system disorders	3	0.00 %
Alice in wonderland syndrome	Psychiatric disorders	3	0.00 %
Allergic hepatitis	Hepatobiliary disorders	3	0.00 %
Altered pitch perception	Nervous system disorders	3	0.00 %
Alveolar osteitis	Infections and infestations	3	0.00 %
Amphetamines positive	Investigations	3	0.00 %
Anaemia megaloblastic	Blood and lymphatic system disorders	3	0.00 %
Anaesthetic complication	Injury, poisoning and procedural complications	3	0.00 %
Anal candidiasis	Infections and infestations	3	0.00 %
Anal erythema	Gastrointestinal disorders	3	0.00 %
Analgesic intervention supportive therapy	Surgical and medical procedures	3	0.00 %
Angiocentric lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Angiogram abnormal	Investigations	3	0.00 %
Ankyloglossia congenital	Congenital, familial and genetic disorders	3	0.00 %
Anoxia	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Anti factor VIII antibody positive	Investigations	3	0.00 %
Anti-aquaporin-4 antibody positive	Investigations	3	0.00 %
Anti-islet cell antibody positive	Investigations	3	0.00 %
Anti-myelin-associated glycoprotein antibodies positive	Investigations	3	0.00 %
Antiacetylcholine receptor antibody positive	Investigations	3	0.00 %
Antiallergic therapy	Surgical and medical procedures	3	0.00 %
Anticoagulation drug level above therapeutic	Investigations	3	0.00 %
Antimitochondrial antibody positive	Investigations	3	0.00 %
Antipsychotic drug level increased	Investigations	3	0.00 %
Antithrombin III decreased	Investigations	3	0.00 %
Appendiceal abscess	Infections and infestations	3	0.00 %
Application site coldness	General disorders and administration site conditions	3	0.00 %
Application site dysaesthesia	General disorders and administration site conditions	3	0.00 %
Application site joint pain	General disorders and administration site conditions	3	0.00 %
Aqueductal stenosis	Nervous system disorders	3	0.00 %
Arrested labour	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Arrhythmia neonatal	Cardiac disorders	3	0.00 %
Arteriosclerotic retinopathy	Eye disorders	3	0.00 %
Arteritis coronary	Cardiac disorders	3	0.00 %
Arthritis viral	Infections and infestations	3	0.00 %
Aspartate aminotransferase decreased	Investigations	3	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Aspergillus test positive	Investigations	3	0.00 %
Asthma late onset	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Asthma prophylaxis	Surgical and medical procedures	3	0.00 %
Atheroembolism	Vascular disorders	3	0.00 %
Atrial pressure increased	Investigations	3	0.00 %
Auricular chondritis	Ear and labyrinth disorders	3	0.00 %
Autoimmune eye disorder	Eye disorders	3	0.00 %
Autoimmune lung disease	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Autoimmune lymphoproliferative syndrome	Congenital, familial and genetic disorders	3	0.00 %
Automatism	Psychiatric disorders	3	0.00 %
B-lymphocyte count increased	Investigations	3	0.00 %
Bacterial disease carrier	Infections and infestations	3	0.00 %
Bacterial test	Investigations	3	0.00 %
Band neutrophil count increased	Investigations	3	0.00 %
Basal ganglia haematoma	Nervous system disorders	3	0.00 %
Base excess increased	Investigations	3	0.00 %
Basophil count abnormal	Investigations	3	0.00 %
Basophilia	Blood and lymphatic system disorders	3	0.00 %
Bed bug infestation	Infections and infestations	3	0.00 %
Benign salivary gland neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Bile duct stenosis	Hepatobiliary disorders	3	0.00 %
Biliary tract infection	Infections and infestations	3	0.00 %
Biochemical pregnancy	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Biopsy lymph gland	Investigations	3	0.00 %
Bladder prolapse	Renal and urinary disorders	3	0.00 %
Bleeding anovulatory	Reproductive system and breast disorders	3	0.00 %
Bleeding time abnormal	Investigations	3	0.00 %
Blepharochalasis	Eye disorders	3	0.00 %
Blood 25-hydroxycholecalciferol decreased	Investigations	3	0.00 %
Blood cholesterol	Investigations	3	0.00 %
Blood creatine phosphokinase	Investigations	3	0.00 %
Blood glucagon increased	Investigations	3	0.00 %
Blood immunoglobulin A decreased	Investigations	3	0.00 %
Blood magnesium increased	Investigations	3	0.00 %
Blood osmolarity decreased	Investigations	3	0.00 %
Blood prolactin	Investigations	3	0.00 %
Blood urea nitrogen/creatinine ratio increased	Investigations	3	0.00 %
Body dysmorphic disorder	Psychiatric disorders	3	0.00 %
Body temperature normal	Investigations	3	0.00 %
Bone abscess	Infections and infestations	3	0.00 %
Bone cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Brain cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Brain neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Breast calcifications	Reproductive system and breast disorders	3	0.00 %
Breast cancer stage II	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Breast cancer stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Breast cellulitis	Infections and infestations	3	0.00 %
Breast discharge infected	Infections and infestations	3	0.00 %
Breast necrosis	Reproductive system and breast disorders	3	0.00 %
Breast operation	Surgical and medical procedures	3	0.00 %
Breech presentation	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Bronchial haemorrhage	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Bundle branch block bilateral	Cardiac disorders	3	0.00 %
Bursal haematoma	Musculoskeletal and connective tissue disorders	3	0.00 %
Campnocormia	Musculoskeletal and connective tissue disorders	3	0.00 %
Campylobacter test positive	Investigations	3	0.00 %
Cancer pain	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Candida sepsis	Infections and infestations	3	0.00 %
Carbohydrate intolerance	Metabolism and nutrition disorders	3	0.00 %
Carboxyhaemoglobin increased	Investigations	3	0.00 %
Cardiac imaging procedure abnormal	Investigations	3	0.00 %
Cardiac perforation	Cardiac disorders	3	0.00 %
Cardiac steatosis	Cardiac disorders	3	0.00 %
Cardiac valve fibroelastoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Cardiac valve sclerosis	Cardiac disorders	3	0.00 %
Carotid aneurysm rupture	Nervous system disorders	3	0.00 %
Carotid pulse abnormal	Investigations	3	0.00 %
Cat scratch disease	Infections and infestations	3	0.00 %
Cataract subcapsular	Eye disorders	3	0.00 %
CD4 lymphocytes increased	Investigations	3	0.00 %
CD8 lymphocytes decreased	Investigations	3	0.00 %
Cell-mediated immune deficiency	Immune system disorders	3	0.00 %
Cells in urine	Investigations	3	0.00 %
Central nervous system injury	Injury, poisoning and procedural complications	3	0.00 %
Central nervous system lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Central nervous system stimulation	Surgical and medical procedures	3	0.00 %
Cephalo-pelvic disproportion	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Cerebral calcification	Nervous system disorders	3	0.00 %
Cerebral hyperperfusion syndrome	Injury, poisoning and procedural complications	3	0.00 %
Cerebral vascular occlusion	Nervous system disorders	3	0.00 %
Cerebrovascular insufficiency	Nervous system disorders	3	0.00 %
Cerebrovascular stenosis	Nervous system disorders	3	0.00 %
Cervical cord compression	Nervous system disorders	3	0.00 %
Cervical spinal cord paralysis	Nervous system disorders	3	0.00 %
Cervical vertebral fracture	Injury, poisoning and procedural complications	3	0.00 %
Cervicitis	Infections and infestations	3	0.00 %
Cervix inflammation	Reproductive system and breast disorders	3	0.00 %
Charles Bonnet syndrome	Eye disorders	3	0.00 %
Chest wall haematoma	Musculoskeletal and connective tissue disorders	3	0.00 %
Chloropsia	Eye disorders	3	0.00 %
Cholestasis of pregnancy	Hepatobiliary disorders	3	0.00 %
Choreoathetosis	Nervous system disorders	3	0.00 %
Chorioretinal disorder	Eye disorders	3	0.00 %
Chronic hepatitis	Hepatobiliary disorders	3	0.00 %
Citrobacter infection	Infections and infestations	3	0.00 %
Claude's syndrome	Nervous system disorders	3	0.00 %
Clear cell renal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Cloacal exstrophy	Congenital, familial and genetic disorders	3	0.00 %
Clostridial infection	Infections and infestations	3	0.00 %
Clot retraction	Investigations	3	0.00 %
Clubbing	Musculoskeletal and connective tissue disorders	3	0.00 %
Coagulation factor VIII level decreased	Investigations	3	0.00 %
Coarctation of the aorta	Congenital, familial and genetic disorders	3	0.00 %
Collateral circulation	Vascular disorders	3	0.00 %
Colon cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Colon gangrene	Infections and infestations	3	0.00 %
Colon injury	Injury, poisoning and procedural complications	3	0.00 %
Complication of delivery	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Compulsions	Psychiatric disorders	3	0.00 %
Computerised tomogram thorax	Investigations	3	0.00 %
Congenital cystic kidney disease	Congenital, familial and genetic disorders	3	0.00 %
Congenital hydronephrosis	Congenital, familial and genetic disorders	3	0.00 %
Conjunctival cyst	Eye disorders	3	0.00 %
Conjunctival discolouration	Eye disorders	3	0.00 %
Contraindicated product prescribed	Injury, poisoning and procedural complications	3	0.00 %
Contrast media reaction	Immune system disorders	3	0.00 %
Coombs direct test positive	Investigations	3	0.00 %
Coombs test positive	Investigations	3	0.00 %
Corneal infection	Infections and infestations	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Corneal infiltrates	Eye disorders	3	0.00 %
Coronary artery insufficiency	Cardiac disorders	3	0.00 %
Coronavirus test	Investigations	3	0.00 %
Cortisol abnormal	Investigations	3	0.00 %
Cow pox	Infections and infestations	3	0.00 %
Cranial nerve infection	Infections and infestations	3	0.00 %
Craniectomy	Surgical and medical procedures	3	0.00 %
Crush injury	Injury, poisoning and procedural complications	3	0.00 %
CSF cell count abnormal	Investigations	3	0.00 %
CSF oligoclonal band	Investigations	3	0.00 %
CSF pressure	Investigations	3	0.00 %
Cutaneous contour deformity	Skin and subcutaneous tissue disorders	3	0.00 %
Cutaneous T-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Cyanosis central	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Cyclothymic disorder	Psychiatric disorders	3	0.00 %
Cystatin C increased	Investigations	3	0.00 %
Cystic lung disease	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Cytology abnormal	Investigations	3	0.00 %
Decerebrate posture	Nervous system disorders	3	0.00 %
Deficiency of bile secretion	Hepatobiliary disorders	3	0.00 %
Demodicidosis	Infections and infestations	3	0.00 %
Dengue virus test positive	Investigations	3	0.00 %
Dental dysaesthesia	Gastrointestinal disorders	3	0.00 %
Dental necrosis	Gastrointestinal disorders	3	0.00 %
Dental restoration failure	Injury, poisoning and procedural complications	3	0.00 %
Dermal filler injection	Surgical and medical procedures	3	0.00 %
Dermatophytosis of nail	Infections and infestations	3	0.00 %
Developmental delay	General disorders and administration site conditions	3	0.00 %
Device failure	Product issues	3	0.00 %
Device occlusion	Product issues	3	0.00 %
Device physical property issue	Product issues	3	0.00 %
Diabetic gastroparesis	Gastrointestinal disorders	3	0.00 %
Diabetic hyperosmolar coma	Nervous system disorders	3	0.00 %
Diaphragm muscle weakness	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Disease prodromal stage	General disorders and administration site conditions	3	0.00 %
Disorder of orbit	Eye disorders	3	0.00 %
Distributive shock	Vascular disorders	3	0.00 %
Diverticular perforation	Gastrointestinal disorders	3	0.00 %
Dose calculation error	Injury, poisoning and procedural complications	3	0.00 %
Drug monitoring procedure incorrectly performed	Injury, poisoning and procedural complications	3	0.00 %
Drug specific antibody absent	Investigations	3	0.00 %
Drug tolerance decreased	General disorders and administration site conditions	3	0.00 %
Duodenal ulcer perforation	Gastrointestinal disorders	3	0.00 %
Duplicate therapy error	Injury, poisoning and procedural complications	3	0.00 %
Dysaesthesia pharynx	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Dyscalculia	Nervous system disorders	3	0.00 %
Ear deformity acquired	Ear and labyrinth disorders	3	0.00 %
Ear infection bacterial	Infections and infestations	3	0.00 %
Ear neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Early satiety	General disorders and administration site conditions	3	0.00 %
Eclampsia	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Economic problem	Social circumstances	3	0.00 %
Eczema impetiginous	Infections and infestations	3	0.00 %
Electrocardiogram QT interval abnormal	Investigations	3	0.00 %
Electrocardiogram ST-T segment elevation	Investigations	3	0.00 %
Electrocardiogram T wave amplitude increased	Investigations	3	0.00 %
Electrocardiogram T wave peaked	Investigations	3	0.00 %
Electrolyte depletion	Metabolism and nutrition disorders	3	0.00 %
Electrophoresis protein abnormal	Investigations	3	0.00 %
Elephantiasis	Blood and lymphatic system disorders	3	0.00 %
Emergency care examination	Investigations	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Encapsulation reaction	General disorders and administration site conditions	3	0.00 %
Encephalocele	Congenital, familial and genetic disorders	3	0.00 %
Endometrial hypoplasia	Reproductive system and breast disorders	3	0.00 %
Endophthalmitis	Infections and infestations	3	0.00 %
Endotracheal intubation complication	Injury, poisoning and procedural complications	3	0.00 %
Enterovesical fistula	Gastrointestinal disorders	3	0.00 %
Enterovirus infection	Infections and infestations	3	0.00 %
Eosinophilic pustular folliculitis	Skin and subcutaneous tissue disorders	3	0.00 %
Epidermolysis	Skin and subcutaneous tissue disorders	3	0.00 %
Epidermolysis bullosa	Congenital, familial and genetic disorders	3	0.00 %
Epididymal tenderness	Reproductive system and breast disorders	3	0.00 %
Epidural haemorrhage	Injury, poisoning and procedural complications	3	0.00 %
Erosive oesophagitis	Gastrointestinal disorders	3	0.00 %
Erythrasma	Infections and infestations	3	0.00 %
Exanthema subitum	Infections and infestations	3	0.00 %
Excessive granulation tissue	Skin and subcutaneous tissue disorders	3	0.00 %
Exomphalos	Congenital, familial and genetic disorders	3	0.00 %
Extradural abscess	Infections and infestations	3	0.00 %
Eye luxation	Injury, poisoning and procedural complications	3	0.00 %
Eyelid tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Failed in vitro fertilisation	Injury, poisoning and procedural complications	3	0.00 %
False negative pregnancy test	Investigations	3	0.00 %
Fat tissue decreased	General disorders and administration site conditions	3	0.00 %
Fear of pregnancy	Psychiatric disorders	3	0.00 %
Febrile bone marrow aplasia	Blood and lymphatic system disorders	3	0.00 %
Fistula discharge	Musculoskeletal and connective tissue disorders	3	0.00 %
Flight of ideas	Psychiatric disorders	3	0.00 %
Foetal-maternal haemorrhage	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Forced expiratory volume increased	Investigations	3	0.00 %
Foreign body in respiratory tract	Injury, poisoning and procedural complications	3	0.00 %
Fructose intolerance	Metabolism and nutrition disorders	3	0.00 %
Full blood count normal	Investigations	3	0.00 %
Gallbladder injury	Injury, poisoning and procedural complications	3	0.00 %
Gammopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Gastric varices haemorrhage	Gastrointestinal disorders	3	0.00 %
Gastritis bacterial	Infections and infestations	3	0.00 %
Gastrocardiac syndrome	Cardiac disorders	3	0.00 %
Gastroenteritis eosinophilic	Gastrointestinal disorders	3	0.00 %
Gastroenteritis Escherichia coli	Infections and infestations	3	0.00 %
Gastroenteritis norovirus	Infections and infestations	3	0.00 %
Gastrointestinal scarring	Gastrointestinal disorders	3	0.00 %
Genital candidiasis	Infections and infestations	3	0.00 %
Genital erosion	Reproductive system and breast disorders	3	0.00 %
Genital infection	Infections and infestations	3	0.00 %
Genital infection viral	Infections and infestations	3	0.00 %
Genitourinary tract infection	Infections and infestations	3	0.00 %
Gestational trophoblastic detachment	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Giant papillary conjunctivitis	Eye disorders	3	0.00 %
Gingival hypertrophy	Gastrointestinal disorders	3	0.00 %
Gingival injury	Injury, poisoning and procedural complications	3	0.00 %
Glossopharyngeal nerve disorder	Nervous system disorders	3	0.00 %
Glucocorticoid deficiency	Endocrine disorders	3	0.00 %
Gonorrhoea	Infections and infestations	3	0.00 %
Goodpasture's syndrome	Renal and urinary disorders	3	0.00 %
Gouty tophus	Musculoskeletal and connective tissue disorders	3	0.00 %
Granulomatous liver disease	Hepatobiliary disorders	3	0.00 %
Grip strength	Investigations	3	0.00 %
Groin infection	Infections and infestations	3	0.00 %
Growth disorder	Musculoskeletal and connective tissue disorders	3	0.00 %
Haematoma infection	Infections and infestations	3	0.00 %
Haemoglobinaemia	Blood and lymphatic system disorders	3	0.00 %
Haemorrhage neonatal	Vascular disorders	3	0.00 %
Haemorrhagic pneumonia	Infections and infestations	3	0.00 %
Haemosiderosis	Metabolism and nutrition disorders	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Helicobacter gastritis	Infections and infestations	3	0.00 %
Henoch-Schonlein purpura nephritis	Renal and urinary disorders	3	0.00 %
Hepatic infection	Infections and infestations	3	0.00 %
Hepatic vascular thrombosis	Hepatobiliary disorders	3	0.00 %
Hepatitis B reactivation	Infections and infestations	3	0.00 %
Hepatorenal failure	Hepatobiliary disorders	3	0.00 %
Hereditary ataxia	Congenital, familial and genetic disorders	3	0.00 %
Hereditary neuropathy with liability to pressure palsies	Congenital, familial and genetic disorders	3	0.00 %
Herpes gestationis	Skin and subcutaneous tissue disorders	3	0.00 %
Herpes simplex hepatitis	Infections and infestations	3	0.00 %
Herpes simplex meningitis	Infections and infestations	3	0.00 %
Herpes simplex meningoencephalitis	Infections and infestations	3	0.00 %
Hip surgery	Surgical and medical procedures	3	0.00 %
Hippocampal sclerosis	Nervous system disorders	3	0.00 %
Hoffmann's sign	Nervous system disorders	3	0.00 %
Homosexuality	Social circumstances	3	0.00 %
Human epidermal growth factor receptor decreased	Investigations	3	0.00 %
Hydrometra	Reproductive system and breast disorders	3	0.00 %
Hyperchloraemia	Metabolism and nutrition disorders	3	0.00 %
Hyperchromic anaemia	Blood and lymphatic system disorders	3	0.00 %
Hyperexplexia	Congenital, familial and genetic disorders	3	0.00 %
Hyperglobulinaemia	Blood and lymphatic system disorders	3	0.00 %
Hyperglycinaemia	Congenital, familial and genetic disorders	3	0.00 %
Hyperoxia	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Hyperplasia adrenal	Endocrine disorders	3	0.00 %
Hypersexuality	Psychiatric disorders	3	0.00 %
Hypertrophic scar	Skin and subcutaneous tissue disorders	3	0.00 %
Hypnopompic hallucination	Psychiatric disorders	3	0.00 %
Hypocoagulable state	Blood and lymphatic system disorders	3	0.00 %
Hypocomplementaemia	Immune system disorders	3	0.00 %
Hypoglossal nerve disorder	Nervous system disorders	3	0.00 %
Hypotonia neonatal	Musculoskeletal and connective tissue disorders	3	0.00 %
Iatrogenic injury	Injury, poisoning and procedural complications	3	0.00 %
Idiosyncratic drug reaction	General disorders and administration site conditions	3	0.00 %
Iliotibial band syndrome	Injury, poisoning and procedural complications	3	0.00 %
Imminent abortion	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Immune-mediated arthritis	Musculoskeletal and connective tissue disorders	3	0.00 %
Immune-mediated hepatic disorder	Hepatobiliary disorders	3	0.00 %
Immune-mediated hepatitis	Hepatobiliary disorders	3	0.00 %
Immune-mediated lung disease	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Immune-mediated thyroiditis	Endocrine disorders	3	0.00 %
Immunodeficiency common variable	Immune system disorders	3	0.00 %
Implant site hypersensitivity	General disorders and administration site conditions	3	0.00 %
Implant site induration	General disorders and administration site conditions	3	0.00 %
Inability to crawl	Nervous system disorders	3	0.00 %
Inclusion body myositis	Musculoskeletal and connective tissue disorders	3	0.00 %
Incorrect disposal of product	Injury, poisoning and procedural complications	3	0.00 %
Incorrect dose administered by product	Injury, poisoning and procedural complications	3	0.00 %
Infantile apnoea	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Infected seroma	Infections and infestations	3	0.00 %
Infective tenosynovitis	Infections and infestations	3	0.00 %
Inflammatory marker decreased	Investigations	3	0.00 %
Infusion site bruising	General disorders and administration site conditions	3	0.00 %
Infusion site extravasation	General disorders and administration site conditions	3	0.00 %
Infusion site haemorrhage	General disorders and administration site conditions	3	0.00 %
Infusion site swelling	General disorders and administration site conditions	3	0.00 %
Infusion site warmth	General disorders and administration site conditions	3	0.00 %
Ingrown hair	Skin and subcutaneous tissue disorders	3	0.00 %
Injection site atrophy	General disorders and administration site conditions	3	0.00 %
Injection site cyst	General disorders and administration site conditions	3	0.00 %
Injection site scar	General disorders and administration site conditions	3	0.00 %
Inspiratory capacity abnormal	Investigations	3	0.00 %
Instillation site warmth	General disorders and administration site conditions	3	0.00 %
Internal hernia	Gastrointestinal disorders	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Intervertebral disc injury	Injury, poisoning and procedural complications	3	0.00 %
Intestinal atony	Gastrointestinal disorders	3	0.00 %
Intestinal atresia	Congenital, familial and genetic disorders	3	0.00 %
Iodine uptake decreased	Investigations	3	0.00 %
Jessner's lymphocytic infiltration	Skin and subcutaneous tissue disorders	3	0.00 %
Joint space narrowing	Musculoskeletal and connective tissue disorders	3	0.00 %
Jugular vein occlusion	Vascular disorders	3	0.00 %
Keratosis follicular	Congenital, familial and genetic disorders	3	0.00 %
Ketosis	Metabolism and nutrition disorders	3	0.00 %
Kounis syndrome	Cardiac disorders	3	0.00 %
Laryngeal erythema	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Laryngitis allergic	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Leiomyosarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Lens disorder	Eye disorders	3	0.00 %
Lenticular opacities	Eye disorders	3	0.00 %
Leriche syndrome	Vascular disorders	3	0.00 %
Lichenification	Skin and subcutaneous tissue disorders	3	0.00 %
Ligament laxity	Musculoskeletal and connective tissue disorders	3	0.00 %
Lipase abnormal	Investigations	3	0.00 %
Lipoprotein (a) increased	Investigations	3	0.00 %
Liposarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Listeriosis	Infections and infestations	3	0.00 %
Liver contusion	Injury, poisoning and procedural complications	3	0.00 %
Liver transplant rejection	Immune system disorders	3	0.00 %
Loeffler's syndrome	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Long thoracic nerve palsy	Nervous system disorders	3	0.00 %
Loose body in joint	Musculoskeletal and connective tissue disorders	3	0.00 %
Lower respiratory tract infection bacterial	Infections and infestations	3	0.00 %
Lower respiratory tract infection viral	Infections and infestations	3	0.00 %
Lower respiratory tract inflammation	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Lumbosacral plexopathy	Nervous system disorders	3	0.00 %
Lung carcinoma cell type unspecified recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Lung cyst	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Lung transplant rejection	Immune system disorders	3	0.00 %
Lyme carditis	Infections and infestations	3	0.00 %
Lymphangiectasia	Vascular disorders	3	0.00 %
Lymphangiopathy	Vascular disorders	3	0.00 %
Lymphatic fistula	Vascular disorders	3	0.00 %
Lymphatic insufficiency	Blood and lymphatic system disorders	3	0.00 %
Lymphatic system neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Lymphocyte percentage abnormal	Investigations	3	0.00 %
Macular ischaemia	Eye disorders	3	0.00 %
Magnetic resonance imaging head	Investigations	3	0.00 %
Malignant pleural effusion	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Marginal zone lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Mastectomy	Surgical and medical procedures	3	0.00 %
Mastitis bacterial	Infections and infestations	3	0.00 %
Maternal condition affecting foetus	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Maximum heart rate	Investigations	3	0.00 %
Mean arterial pressure decreased	Investigations	3	0.00 %
Mean cell haemoglobin	Investigations	3	0.00 %
Mechanical ileus	Gastrointestinal disorders	3	0.00 %
Mechanical ventilation	Surgical and medical procedures	3	0.00 %
Meconium aspiration syndrome	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Meconium in amniotic fluid	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Mediastinal haemorrhage	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Medical device site joint inflammation	General disorders and administration site conditions	3	0.00 %
Medication overuse headache	Nervous system disorders	3	0.00 %
Megacolon	Gastrointestinal disorders	3	0.00 %
Megakaryocytes increased	Investigations	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Meningoencephalitis bacterial	Infections and infestations	3	0.00 %
Mesangioproliferative glomerulonephritis	Renal and urinary disorders	3	0.00 %
Mesenteritis	Gastrointestinal disorders	3	0.00 %
Metal poisoning	Injury, poisoning and procedural complications	3	0.00 %
Metaplasia	General disorders and administration site conditions	3	0.00 %
Metastatic lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Metrorrhoea	Reproductive system and breast disorders	3	0.00 %
Microsleep	Nervous system disorders	3	0.00 %
Middle ear disorder	Ear and labyrinth disorders	3	0.00 %
Mineral deficiency	Metabolism and nutrition disorders	3	0.00 %
Mixed incontinence	Renal and urinary disorders	3	0.00 %
Monoclonal immunoglobulin present	Investigations	3	0.00 %
Moyamoya disease	Nervous system disorders	3	0.00 %
Mucocutaneous haemorrhage	Skin and subcutaneous tissue disorders	3	0.00 %
Mucosal erosion	General disorders and administration site conditions	3	0.00 %
Mucosal infection	Infections and infestations	3	0.00 %
Multiple sclerosis relapse prophylaxis	Surgical and medical procedures	3	0.00 %
Muscle hypoxia	Musculoskeletal and connective tissue disorders	3	0.00 %
Mycobacterium tuberculosis complex test positive	Investigations	3	0.00 %
Mycotic allergy	Immune system disorders	3	0.00 %
Myelomalacia	Nervous system disorders	3	0.00 %
Myocardial bridging	Congenital, familial and genetic disorders	3	0.00 %
Myoclonic dystonia	Congenital, familial and genetic disorders	3	0.00 %
Myoglobin blood decreased	Investigations	3	0.00 %
Myotonia	Nervous system disorders	3	0.00 %
Naevus flammeus	Congenital, familial and genetic disorders	3	0.00 %
Nail operation	Surgical and medical procedures	3	0.00 %
Nasal cavity packing	Surgical and medical procedures	3	0.00 %
Natural killer T cell count increased	Investigations	3	0.00 %
Necrotising ulcerative gingivostomatitis	Infections and infestations	3	0.00 %
Neologism	Psychiatric disorders	3	0.00 %
Neonatal pneumothorax	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Neovascularisation	Vascular disorders	3	0.00 %
Nephrogenic anaemia	Blood and lymphatic system disorders	3	0.00 %
Nerve root injury	Injury, poisoning and procedural complications	3	0.00 %
Neurological examination normal	Investigations	3	0.00 %
Neurological infection	Infections and infestations	3	0.00 %
Neuronal neuropathy	Nervous system disorders	3	0.00 %
Neuropathic arthropathy	Musculoskeletal and connective tissue disorders	3	0.00 %
Neuropathic pruritus	Skin and subcutaneous tissue disorders	3	0.00 %
Neutralising antibodies negative	Investigations	3	0.00 %
Neutrophil count	Investigations	3	0.00 %
Neutrophil percentage abnormal	Investigations	3	0.00 %
Nicotine dependence	Psychiatric disorders	3	0.00 %
Nikolsky's sign	Skin and subcutaneous tissue disorders	3	0.00 %
Nocturnal emission	Reproductive system and breast disorders	3	0.00 %
Non-24-hour sleep-wake disorder	Nervous system disorders	3	0.00 %
Non-consummation	Social circumstances	3	0.00 %
Non-Hodgkin's lymphoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Norepinephrine increased	Investigations	3	0.00 %
Nosophobia	Psychiatric disorders	3	0.00 %
Notalgia paraesthesia	Nervous system disorders	3	0.00 %
Numb chin syndrome	Nervous system disorders	3	0.00 %
Oedematous kidney	Renal and urinary disorders	3	0.00 %
Oligospermia	Reproductive system and breast disorders	3	0.00 %
Open fracture	Injury, poisoning and procedural complications	3	0.00 %
Ophthalmological examination abnormal	Investigations	3	0.00 %
Optic perineuritis	Nervous system disorders	3	0.00 %
Oral discharge	Gastrointestinal disorders	3	0.00 %
Oral mucosal scab	Gastrointestinal disorders	3	0.00 %
Orgasmic sensation decreased	Psychiatric disorders	3	0.00 %
Osteomyelitis acute	Infections and infestations	3	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Ovarian neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Ovulation induction	Surgical and medical procedures	3	0.00 %
Pain assessment	Investigations	3	0.00 %
Palatal palsy	Nervous system disorders	3	0.00 %
Palpatory finding abnormal	Investigations	3	0.00 %
Papillary cystadenoma lymphomatosum	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Papilloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Papillophlebitis	Eye disorders	3	0.00 %
Parasitic gastroenteritis	Infections and infestations	3	0.00 %
Parathyroid tumour benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Paternal exposure before pregnancy	Injury, poisoning and procedural complications	3	0.00 %
Patient isolation	Surgical and medical procedures	3	0.00 %
Patient-device incompatibility	Product issues	3	0.00 %
Peak expiratory flow rate abnormal	Investigations	3	0.00 %
Peau d'orange	Skin and subcutaneous tissue disorders	3	0.00 %
Pelvic infection	Infections and infestations	3	0.00 %
Pelvic misalignment	Musculoskeletal and connective tissue disorders	3	0.00 %
Pelvic organ prolapse	Reproductive system and breast disorders	3	0.00 %
Penile burning sensation	Reproductive system and breast disorders	3	0.00 %
Penile vascular disorder	Reproductive system and breast disorders	3	0.00 %
Penis injury	Injury, poisoning and procedural complications	3	0.00 %
Pericardial cyst	Cardiac disorders	3	0.00 %
Pericardial mass	Cardiac disorders	3	0.00 %
Pericoronitis	Infections and infestations	3	0.00 %
Periodontal inflammation	Gastrointestinal disorders	3	0.00 %
Periorbital inflammation	Eye disorders	3	0.00 %
Peripheral vein thrombus extension	Vascular disorders	3	0.00 %
Periportal oedema	Hepatobiliary disorders	3	0.00 %
Peritoneal disorder	Gastrointestinal disorders	3	0.00 %
Perseveration	Psychiatric disorders	3	0.00 %
Persistent generalised lymphadenopathy	Infections and infestations	3	0.00 %
pH body fluid abnormal	Investigations	3	0.00 %
Pharyngeal cyst	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Pharyngeal lesion	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Phlebectomy	Surgical and medical procedures	3	0.00 %
Phlebolith	Vascular disorders	3	0.00 %
Phlebotomy	Surgical and medical procedures	3	0.00 %
Physical assault	Social circumstances	3	0.00 %
Physical product label issue	Product issues	3	0.00 %
Pituitary tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Pityriasis alba	Skin and subcutaneous tissue disorders	3	0.00 %
Placenta praevia	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Plasma cell mastitis	Reproductive system and breast disorders	3	0.00 %
Platelet distribution width increased	Investigations	3	0.00 %
Platelet dysfunction	Blood and lymphatic system disorders	3	0.00 %
Platelet function test abnormal	Investigations	3	0.00 %
Plateletcrit decreased	Investigations	3	0.00 %
Platypnoea	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Pleomorphic adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Pleural fibrosis	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Pleural neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Pneumoconiosis	Injury, poisoning and procedural complications	3	0.00 %
Pneumocystis jirovecii infection	Infections and infestations	3	0.00 %
Poor weight gain neonatal	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Portal hypertensive gastropathy	Gastrointestinal disorders	3	0.00 %
Portal vein phlebitis	Hepatobiliary disorders	3	0.00 %
Post cardiac arrest syndrome	Nervous system disorders	3	0.00 %
Post procedural oedema	Injury, poisoning and procedural complications	3	0.00 %
Post procedural swelling	Injury, poisoning and procedural complications	3	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Post transplant lymphoproliferative disorder	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Post-traumatic amnestic disorder	Psychiatric disorders	3	0.00 %
Post-traumatic epilepsy	Nervous system disorders	3	0.00 %
Posterior tibial nerve injury	Injury, poisoning and procedural complications	3	0.00 %
Postoperative wound complication	Injury, poisoning and procedural complications	3	0.00 %
Premature ageing	General disorders and administration site conditions	3	0.00 %
Premature ejaculation	Psychiatric disorders	3	0.00 %
Prescribed underdose	Injury, poisoning and procedural complications	3	0.00 %
Prescription drug used without a prescription	Injury, poisoning and procedural complications	3	0.00 %
Primary hyperaldosteronism	Endocrine disorders	3	0.00 %
Procedural headache	Injury, poisoning and procedural complications	3	0.00 %
Procedural vomiting	Injury, poisoning and procedural complications	3	0.00 %
Proctitis haemorrhagic	Gastrointestinal disorders	3	0.00 %
Product appearance confusion	Injury, poisoning and procedural complications	3	0.00 %
Product packaging issue	Product issues	3	0.00 %
Progesterone abnormal	Investigations	3	0.00 %
Progressive bulbar palsy	Nervous system disorders	3	0.00 %
Prosthetic cardiac valve thrombosis	General disorders and administration site conditions	3	0.00 %
Protein C decreased	Investigations	3	0.00 %
Protein C deficiency	Congenital, familial and genetic disorders	3	0.00 %
Proteus infection	Infections and infestations	3	0.00 %
Prothrombin level abnormal	Investigations	3	0.00 %
Pseudostroke	Nervous system disorders	3	0.00 %
Psoas abscess	Infections and infestations	3	0.00 %
Psychogenic pseudosyncope	Psychiatric disorders	3	0.00 %
Psychotic disorder due to a general medical condition	Psychiatric disorders	3	0.00 %
Pulmonary cavitation	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Pulmonary contusion	Injury, poisoning and procedural complications	3	0.00 %
Pulse waveform abnormal	Investigations	3	0.00 %
Puncture site haematoma	General disorders and administration site conditions	3	0.00 %
Radiation pneumonitis	Injury, poisoning and procedural complications	3	0.00 %
Rash follicular	Skin and subcutaneous tissue disorders	3	0.00 %
Reaction to colouring	Immune system disorders	3	0.00 %
Reaction to previous exposure to any vaccine	Injury, poisoning and procedural complications	3	0.00 %
Rebound psoriasis	Skin and subcutaneous tissue disorders	3	0.00 %
Recalled product administered	Injury, poisoning and procedural complications	3	0.00 %
Rectal abscess	Infections and infestations	3	0.00 %
Rectal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Red blood cell morphology abnormal	Investigations	3	0.00 %
Red man syndrome	Skin and subcutaneous tissue disorders	3	0.00 %
Rehabilitation therapy	Surgical and medical procedures	3	0.00 %
Renal aneurysm	Renal and urinary disorders	3	0.00 %
Renal necrosis	Renal and urinary disorders	3	0.00 %
Renal transplant failure	Immune system disorders	3	0.00 %
Renal tubular injury	Renal and urinary disorders	3	0.00 %
Renal vein occlusion	Renal and urinary disorders	3	0.00 %
Repetitive strain injury	Injury, poisoning and procedural complications	3	0.00 %
Respiratory disorder neonatal	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Reticulocyte count decreased	Investigations	3	0.00 %
Retinal drusen	Eye disorders	3	0.00 %
Retinal neovascularisation	Eye disorders	3	0.00 %
Retinal toxicity	Eye disorders	3	0.00 %
Retinoschisis	Eye disorders	3	0.00 %
Retracted nipple	Reproductive system and breast disorders	3	0.00 %
Reversible ischaemic neurological deficit	Nervous system disorders	3	0.00 %
Rheumatic heart disease	Cardiac disorders	3	0.00 %
Rhinitis perennial	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Salivary gland adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Salivary gland mucocoele	Gastrointestinal disorders	3	0.00 %
Salmonella sepsis	Infections and infestations	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Salmonella test positive	Investigations	3	0.00 %
Salpingectomy	Surgical and medical procedures	3	0.00 %
Salpingitis	Infections and infestations	3	0.00 %
Sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Scan lymph nodes	Investigations	3	0.00 %
Scapula fracture	Injury, poisoning and procedural complications	3	0.00 %
Scapular dyskinesis	Musculoskeletal and connective tissue disorders	3	0.00 %
Scrotal disorder	Reproductive system and breast disorders	3	0.00 %
Scrotal exfoliation	Reproductive system and breast disorders	3	0.00 %
Scrotal inflammation	Reproductive system and breast disorders	3	0.00 %
Scrub typhus	Infections and infestations	3	0.00 %
Secondary progressive multiple sclerosis	Nervous system disorders	3	0.00 %
Semen volume decreased	Investigations	3	0.00 %
Sepsis syndrome	Infections and infestations	3	0.00 %
Septic embolus	Infections and infestations	3	0.00 %
Septic encephalopathy	Infections and infestations	3	0.00 %
Serology negative	Investigations	3	0.00 %
Serratia infection	Infections and infestations	3	0.00 %
Severe fever with thrombocytopenia syndrome	Infections and infestations	3	0.00 %
Shift to the left	Investigations	3	0.00 %
Shock hypoglycaemic	Metabolism and nutrition disorders	3	0.00 %
Short-bowel syndrome	Gastrointestinal disorders	3	0.00 %
Shoulder arthroplasty	Surgical and medical procedures	3	0.00 %
Shunt occlusion	Injury, poisoning and procedural complications	3	0.00 %
Sinus operation	Surgical and medical procedures	3	0.00 %
Skin graft	Surgical and medical procedures	3	0.00 %
Small size placenta	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Smoke sensitivity	Immune system disorders	3	0.00 %
Snake bite	Injury, poisoning and procedural complications	3	0.00 %
Social fear	Psychiatric disorders	3	0.00 %
Soft tissue atrophy	Musculoskeletal and connective tissue disorders	3	0.00 %
Somatic dysfunction	Musculoskeletal and connective tissue disorders	3	0.00 %
Specific gravity urine increased	Investigations	3	0.00 %
Spinal claudication	Nervous system disorders	3	0.00 %
Spinal cord abscess	Infections and infestations	3	0.00 %
Spinal epidural haematoma	Nervous system disorders	3	0.00 %
Spinal fusion surgery	Surgical and medical procedures	3	0.00 %
Spinal operation	Surgical and medical procedures	3	0.00 %
Spinal stroke	Nervous system disorders	3	0.00 %
Spinal vascular disorder	Nervous system disorders	3	0.00 %
Spirometry abnormal	Investigations	3	0.00 %
Spleen ischaemia	Blood and lymphatic system disorders	3	0.00 %
Splinter	Injury, poisoning and procedural complications	3	0.00 %
Spondylolysis	Musculoskeletal and connective tissue disorders	3	0.00 %
Staphylococcal scalded skin syndrome	Infections and infestations	3	0.00 %
Staphylococcal skin infection	Infections and infestations	3	0.00 %
Stoma site discharge	Injury, poisoning and procedural complications	3	0.00 %
Subacute inflammatory demyelinating polyneuropathy	Nervous system disorders	3	0.00 %
Subarachnoid haematoma	Injury, poisoning and procedural complications	3	0.00 %
Subchorionic haemorrhage	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Subclavian artery occlusion	Vascular disorders	3	0.00 %
Subclavian vein occlusion	Vascular disorders	3	0.00 %
Substance-induced psychotic disorder	Psychiatric disorders	3	0.00 %
Sudden infant death syndrome	General disorders and administration site conditions	3	0.00 %
Supernumerary nipple	Congenital, familial and genetic disorders	3	0.00 %
Supraclavicular fossa pain	General disorders and administration site conditions	3	0.00 %
Suspected product contamination	Product issues	3	0.00 %
Suspiciousness	Psychiatric disorders	3	0.00 %
Suture related complication	Injury, poisoning and procedural complications	3	0.00 %
Sympathetic posterior cervical syndrome	Musculoskeletal and connective tissue disorders	3	0.00 %
Synaesthesia	Nervous system disorders	3	0.00 %
Tendinous contracture	Musculoskeletal and connective tissue disorders	3	0.00 %
Testicular cyst	Reproductive system and breast disorders	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Testicular infarction	Reproductive system and breast disorders	3	0.00 %
Thanatophobia	Psychiatric disorders	3	0.00 %
Therapeutic product effect increased	General disorders and administration site conditions	3	0.00 %
Thermoanaesthesia	Nervous system disorders	3	0.00 %
Thermometry abnormal	Investigations	3	0.00 %
Thermophobia	Psychiatric disorders	3	0.00 %
Thrombophlebitis migrans	Vascular disorders	3	0.00 %
Thyroid stimulating hormone deficiency	Endocrine disorders	3	0.00 %
Thyroid stimulating immunoglobulin increased	Investigations	3	0.00 %
Thyroidectomy	Surgical and medical procedures	3	0.00 %
Thyroxine abnormal	Investigations	3	0.00 %
Tinea capitis	Infections and infestations	3	0.00 %
Tissue irritation	General disorders and administration site conditions	3	0.00 %
Tissue rupture	General disorders and administration site conditions	3	0.00 %
Tongue thrust	Gastrointestinal disorders	3	0.00 %
Tonsil cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Tooth deposit	Gastrointestinal disorders	3	0.00 %
Tooth erosion	Gastrointestinal disorders	3	0.00 %
Tooth socket haemorrhage	Gastrointestinal disorders	3	0.00 %
Total bile acids increased	Investigations	3	0.00 %
Total cholesterol/HDL ratio increased	Investigations	3	0.00 %
Toxic cardiomyopathy	Cardiac disorders	3	0.00 %
Toxic goitre	Endocrine disorders	3	0.00 %
Toxocariasis	Infections and infestations	3	0.00 %
Tracheal compression	Respiratory, thoracic and mediastinal disorders	3	0.00 %
Transfusion reaction	Injury, poisoning and procedural complications	3	0.00 %
Transposition of the great vessels	Congenital, familial and genetic disorders	3	0.00 %
Transverse sinus stenosis	Nervous system disorders	3	0.00 %
Traumatic haemothorax	Injury, poisoning and procedural complications	3	0.00 %
Treatment noncompliance	General disorders and administration site conditions	3	0.00 %
Trisomy 18	Congenital, familial and genetic disorders	3	0.00 %
Trunk injury	Injury, poisoning and procedural complications	3	0.00 %
Tryptase decreased	Investigations	3	0.00 %
Tumefactive multiple sclerosis	Nervous system disorders	3	0.00 %
Tumour rupture	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Turner's syndrome	Congenital, familial and genetic disorders	3	0.00 %
Twin pregnancy	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Ultrasound breast abnormal	Investigations	3	0.00 %
Ultrasound Doppler abnormal	Investigations	3	0.00 %
Undifferentiated connective tissue disease	Musculoskeletal and connective tissue disorders	3	0.00 %
Ureteric stenosis	Renal and urinary disorders	3	0.00 %
Urteritis	Infections and infestations	3	0.00 %
Urethral valves	Congenital, familial and genetic disorders	3	0.00 %
Urinary sediment abnormal	Investigations	3	0.00 %
Urinary tract candidiasis	Infections and infestations	3	0.00 %
Urine cytology abnormal	Investigations	3	0.00 %
Urine ketone body	Investigations	3	0.00 %
Urine protein/creatinine ratio increased	Investigations	3	0.00 %
Urogenital haemorrhage	Renal and urinary disorders	3	0.00 %
Urticaria aquagenic	Skin and subcutaneous tissue disorders	3	0.00 %
Uterine cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Uterine mass	Reproductive system and breast disorders	3	0.00 %
Vaccination site ischaemia	General disorders and administration site conditions	3	0.00 %
Varicose veins pelvic	Reproductive system and breast disorders	3	0.00 %
Varicose veins vaginal	Reproductive system and breast disorders	3	0.00 %
Vasa praevia	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Vascular stent occlusion	General disorders and administration site conditions	3	0.00 %
Vascular wall hypertrophy	Vascular disorders	3	0.00 %
Venous aneurysm	Vascular disorders	3	0.00 %
Vertebral artery aneurysm	Nervous system disorders	3	0.00 %
Vertebral osteophyte	Musculoskeletal and connective tissue disorders	3	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vessel puncture site bruise	General disorders and administration site conditions	3	0.00 %
Vessel puncture site haemorrhage	General disorders and administration site conditions	3	0.00 %
Vestibular ischaemia	Ear and labyrinth disorders	3	0.00 %
Vestibulocerebellar syndrome	Congenital, familial and genetic disorders	3	0.00 %
Vibration test abnormal	Investigations	3	0.00 %
Violence-related symptom	Psychiatric disorders	3	0.00 %
Viral myelitis	Infections and infestations	3	0.00 %
Viral sepsis	Infections and infestations	3	0.00 %
Viral skin infection	Infections and infestations	3	0.00 %
Virologic failure	Infections and infestations	3	0.00 %
Visceral congestion	Vascular disorders	3	0.00 %
Visceral oedema	General disorders and administration site conditions	3	0.00 %
Vital capacity decreased	Investigations	3	0.00 %
Vitamin B1 deficiency	Metabolism and nutrition disorders	3	0.00 %
Vitamin B6 deficiency	Metabolism and nutrition disorders	3	0.00 %
Vitamin D abnormal	Investigations	3	0.00 %
Vitreoretinal traction syndrome	Eye disorders	3	0.00 %
Vulval eczema	Reproductive system and breast disorders	3	0.00 %
Waldenstrom's macroglobulinaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	0.00 %
Wall motion score index abnormal	Investigations	3	0.00 %
Water intoxication	Metabolism and nutrition disorders	3	0.00 %
Water pollution	Social circumstances	3	0.00 %
Weber tuning fork test abnormal	Investigations	3	0.00 %
Weight decrease neonatal	Pregnancy, puerperium and perinatal conditions	3	0.00 %
Wig wearer	Social circumstances	3	0.00 %
Wound abscess	Infections and infestations	3	0.00 %
Wrist deformity	Musculoskeletal and connective tissue disorders	3	0.00 %
Wrong drug	Injury, poisoning and procedural complications	3	0.00 %
Wrong patient received product	Injury, poisoning and procedural complications	3	0.00 %
Xeroderma	Skin and subcutaneous tissue disorders	3	0.00 %
Abdominal incarcerated hernia	Gastrointestinal disorders	2	0.00 %
Abdominal wall abscess	Infections and infestations	2	0.00 %
Aberrant aortic arch	Congenital, familial and genetic disorders	2	0.00 %
Abortion spontaneous incomplete	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Abscess rupture	Infections and infestations	2	0.00 %
Acalculia	Nervous system disorders	2	0.00 %
Acanthamoeba keratitis	Infections and infestations	2	0.00 %
Acanthosis	Skin and subcutaneous tissue disorders	2	0.00 %
Acariasis	Infections and infestations	2	0.00 %
Acetabulum fracture	Injury, poisoning and procedural complications	2	0.00 %
Achlorhydria	Gastrointestinal disorders	2	0.00 %
Achromotrichia acquired	Skin and subcutaneous tissue disorders	2	0.00 %
Acoustic stimulation tests abnormal	Investigations	2	0.00 %
Acquired factor VIII deficiency	Blood and lymphatic system disorders	2	0.00 %
Acquired macroglossia	Gastrointestinal disorders	2	0.00 %
Acquired phimosis	Reproductive system and breast disorders	2	0.00 %
Acquired syringomyelia	Nervous system disorders	2	0.00 %
Acral peeling skin syndrome	Congenital, familial and genetic disorders	2	0.00 %
Acrophobia	Psychiatric disorders	2	0.00 %
Actinic cheilitis	Skin and subcutaneous tissue disorders	2	0.00 %
Acute endocarditis	Infections and infestations	2	0.00 %
Acute haemorrhagic conjunctivitis	Infections and infestations	2	0.00 %
Acute right ventricular failure	Cardiac disorders	2	0.00 %
ADAMTS13 activity abnormal	Investigations	2	0.00 %
Adenocarcinoma metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Adenocarcinoma pancreas	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Adenoidal hypertrophy	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Adenomatous polyposis coli	Congenital, familial and genetic disorders	2	0.00 %
Adenovirus test positive	Investigations	2	0.00 %
Adiposis dolorosa	Skin and subcutaneous tissue disorders	2	0.00 %
Adjusted calcium decreased	Investigations	2	0.00 %
Administration site discolouration	General disorders and administration site conditions	2	0.00 %
Administration site hypersensitivity	General disorders and administration site conditions	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Administration site hypoesthesia	General disorders and administration site conditions	2	0.00 %
Administration site induration	General disorders and administration site conditions	2	0.00 %
Administration site inflammation	General disorders and administration site conditions	2	0.00 %
Administration site irritation	General disorders and administration site conditions	2	0.00 %
Administration site joint erythema	General disorders and administration site conditions	2	0.00 %
Administration site wound	General disorders and administration site conditions	2	0.00 %
Adnexa uteri cyst	Reproductive system and breast disorders	2	0.00 %
Adnexa uteri mass	Reproductive system and breast disorders	2	0.00 %
Adrenal cortex necrosis	Endocrine disorders	2	0.00 %
Adrenergic syndrome	Nervous system disorders	2	0.00 %
Adult T-cell lymphoma/leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Air embolism	Vascular disorders	2	0.00 %
Airway complication of anaesthesia	Injury, poisoning and procedural complications	2	0.00 %
Airway peak pressure increased	Investigations	2	0.00 %
Albumin CSF abnormal	Investigations	2	0.00 %
Alcohol problem	Psychiatric disorders	2	0.00 %
Alcoholic hangover	Psychiatric disorders	2	0.00 %
Alloimmune hepatitis	Hepatobiliary disorders	2	0.00 %
Alpha 1 foetoprotein increased	Investigations	2	0.00 %
Alpha 1 globulin decreased	Investigations	2	0.00 %
Alpha 2 globulin decreased	Investigations	2	0.00 %
Alpha tumour necrosis factor increased	Investigations	2	0.00 %
Alpha-1 anti-trypsin increased	Investigations	2	0.00 %
Alpha-1 antitrypsin deficiency	Congenital, familial and genetic disorders	2	0.00 %
Amegakaryocytic thrombocytopenia	Congenital, familial and genetic disorders	2	0.00 %
Amino acid level increased	Investigations	2	0.00 %
Amniocentesis abnormal	Investigations	2	0.00 %
Amniotic cavity disorder	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Amniotic fluid volume increased	Investigations	2	0.00 %
Amplified musculoskeletal pain syndrome	Musculoskeletal and connective tissue disorders	2	0.00 %
Amputation stump pain	Nervous system disorders	2	0.00 %
Amylase abnormal	Investigations	2	0.00 %
Amyloidosis senile	Immune system disorders	2	0.00 %
Amyotrophic lateral sclerosis gene carrier	Congenital, familial and genetic disorders	2	0.00 %
Anaemia neonatal	Blood and lymphatic system disorders	2	0.00 %
Anaemia postoperative	Injury, poisoning and procedural complications	2	0.00 %
Anaesthesia dolorosa	Nervous system disorders	2	0.00 %
Anal eczema	Gastrointestinal disorders	2	0.00 %
Anal paraesthesia	Gastrointestinal disorders	2	0.00 %
Anal spasm	Gastrointestinal disorders	2	0.00 %
Androgen deficiency	Endocrine disorders	2	0.00 %
Androgens increased	Investigations	2	0.00 %
Aneurysm repair	Surgical and medical procedures	2	0.00 %
Angiocardiogram	Investigations	2	0.00 %
Angiogram	Investigations	2	0.00 %
Angioplasty	Surgical and medical procedures	2	0.00 %
Anomalous pulmonary venous connection	Congenital, familial and genetic disorders	2	0.00 %
Anorexia nervosa	Psychiatric disorders	2	0.00 %
Anterior cord syndrome	Injury, poisoning and procedural complications	2	0.00 %
Anti-erythrocyte antibody positive	Investigations	2	0.00 %
Anti-neuronal antibody	Investigations	2	0.00 %
Anti-platelet factor 4 antibody positive	Investigations	2	0.00 %
Anti-zinc transporter 8 antibody positive	Investigations	2	0.00 %
Anticholinergic syndrome	Nervous system disorders	2	0.00 %
Anticonvulsant drug level below therapeutic	Investigations	2	0.00 %
Antidepressant discontinuation syndrome	General disorders and administration site conditions	2	0.00 %
Antisocial behaviour	Psychiatric disorders	2	0.00 %
Antral follicle count low	Investigations	2	0.00 %
Anxiety disorder due to a general medical condition	Psychiatric disorders	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Aortic perforation	Vascular disorders	2	0.00 %
Aortic valve disease mixed	Cardiac disorders	2	0.00 %
Aortic valve replacement	Surgical and medical procedures	2	0.00 %
Apgar score low	Investigations	2	0.00 %
Apical granuloma	Gastrointestinal disorders	2	0.00 %
Aplasia	Congenital, familial and genetic disorders	2	0.00 %
Appendicitis noninfective	Gastrointestinal disorders	2	0.00 %
Appendicolith	Gastrointestinal disorders	2	0.00 %
Application site burn	General disorders and administration site conditions	2	0.00 %
Application site discomfort	General disorders and administration site conditions	2	0.00 %
Application site hypersensitivity	General disorders and administration site conditions	2	0.00 %
Application site joint movement impairment	General disorders and administration site conditions	2	0.00 %
Application site pustules	Infections and infestations	2	0.00 %
Aquagenic wrinkling of palms	Skin and subcutaneous tissue disorders	2	0.00 %
Argininosuccinate synthetase deficiency	Congenital, familial and genetic disorders	2	0.00 %
Arterial insufficiency	Vascular disorders	2	0.00 %
Arterial intramural haematoma	Vascular disorders	2	0.00 %
Arthritis allergic	Musculoskeletal and connective tissue disorders	2	0.00 %
Aspermia	Reproductive system and breast disorders	2	0.00 %
Aspiration joint	Investigations	2	0.00 %
Asthenospermia	Reproductive system and breast disorders	2	0.00 %
Asthma-chronic obstructive pulmonary disease overlap syndrome	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Ataxia telangiectasia	Congenital, familial and genetic disorders	2	0.00 %
Atrioventricular dissociation	Cardiac disorders	2	0.00 %
Atypical femur fracture	Injury, poisoning and procedural complications	2	0.00 %
Atypical mycobacterial infection	Infections and infestations	2	0.00 %
Autoimmune inner ear disease	Ear and labyrinth disorders	2	0.00 %
Axial spondyloarthritis	Musculoskeletal and connective tissue disorders	2	0.00 %
Azoospermia	Reproductive system and breast disorders	2	0.00 %
B-lymphocyte count abnormal	Investigations	2	0.00 %
Babesiosis	Infections and infestations	2	0.00 %
Bacillus test positive	Investigations	2	0.00 %
Bacterial colitis	Infections and infestations	2	0.00 %
Bacterial pericarditis	Infections and infestations	2	0.00 %
Bacterial pyelonephritis	Infections and infestations	2	0.00 %
Bacteroides bacteraemia	Infections and infestations	2	0.00 %
Balanitis candida	Infections and infestations	2	0.00 %
Barotitis media	Injury, poisoning and procedural complications	2	0.00 %
Basophil percentage increased	Investigations	2	0.00 %
Belligerence	Psychiatric disorders	2	0.00 %
Benign gastrointestinal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Benign hepatic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Benign neoplasm of thyroid gland	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Beta globulin decreased	Investigations	2	0.00 %
Bifascicular block	Cardiac disorders	2	0.00 %
Bile output increased	Investigations	2	0.00 %
Biliary cirrhosis	Hepatobiliary disorders	2	0.00 %
Bilirubin conjugated	Investigations	2	0.00 %
Biopsy bone marrow abnormal	Investigations	2	0.00 %
Biopsy breast	Investigations	2	0.00 %
Biopsy breast abnormal	Investigations	2	0.00 %
Birdshot chorioretinopathy	Eye disorders	2	0.00 %
Bladder tamponade	Renal and urinary disorders	2	0.00 %
Blast cell count increased	Investigations	2	0.00 %
Blastocystis infection	Infections and infestations	2	0.00 %
Bleeding time shortened	Investigations	2	0.00 %
Blepharitis allergic	Eye disorders	2	0.00 %
Blood alcohol decreased	Investigations	2	0.00 %
Blood aldosterone increased	Investigations	2	0.00 %
Blood alkaline phosphatase	Investigations	2	0.00 %
Blood alkaline phosphatase abnormal	Investigations	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Blood catecholamines increased	Investigations	2	0.00 %
Blood chromium increased	Investigations	2	0.00 %
Blood copper increased	Investigations	2	0.00 %
Blood creatine phosphokinase MM increased	Investigations	2	0.00 %
Blood culture positive	Investigations	2	0.00 %
Blood follicle stimulating hormone abnormal	Investigations	2	0.00 %
Blood glucagon abnormal	Investigations	2	0.00 %
Blood growth hormone abnormal	Investigations	2	0.00 %
Blood immunoglobulin E	Investigations	2	0.00 %
Blood immunoglobulin G abnormal	Investigations	2	0.00 %
Blood insulin	Investigations	2	0.00 %
Blood insulin abnormal	Investigations	2	0.00 %
Blood insulin decreased	Investigations	2	0.00 %
Blood insulin increased	Investigations	2	0.00 %
Blood iron	Investigations	2	0.00 %
Blood ketone body present	Investigations	2	0.00 %
Blood methaemoglobin present	Investigations	2	0.00 %
Blood oestrogen	Investigations	2	0.00 %
Blood osmolarity increased	Investigations	2	0.00 %
Blood parathyroid hormone decreased	Investigations	2	0.00 %
Blood pH	Investigations	2	0.00 %
Blood pressure diastolic	Investigations	2	0.00 %
Blood pressure difference of extremities	Investigations	2	0.00 %
Blood smear test abnormal	Investigations	2	0.00 %
Blood test normal	Investigations	2	0.00 %
Blood thrombin increased	Investigations	2	0.00 %
Blood thyroid stimulating hormone	Investigations	2	0.00 %
Body fat disorder	Metabolism and nutrition disorders	2	0.00 %
Body mass index abnormal	Investigations	2	0.00 %
Bone infarction	Musculoskeletal and connective tissue disorders	2	0.00 %
Bone marrow myelogram abnormal	Investigations	2	0.00 %
Bowen's disease	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Brachioradial pruritus	Skin and subcutaneous tissue disorders	2	0.00 %
Brachydactyly	Congenital, familial and genetic disorders	2	0.00 %
Bradycardia neonatal	Cardiac disorders	2	0.00 %
Brain malformation	Congenital, familial and genetic disorders	2	0.00 %
Breast adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Breast cancer stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Breast dysplasia	Reproductive system and breast disorders	2	0.00 %
Breast fibrosis	Reproductive system and breast disorders	2	0.00 %
Breast reconstruction	Surgical and medical procedures	2	0.00 %
Brief psychotic disorder with marked stressors	Psychiatric disorders	2	0.00 %
Brief resolved unexplained event	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Bromhidrosis	Skin and subcutaneous tissue disorders	2	0.00 %
Bronchopleural fistula	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Bronchopulmonary disease	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Burkitt's lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Burkitt's lymphoma stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
C3 glomerulopathy	Renal and urinary disorders	2	0.00 %
Caffeine consumption	Social circumstances	2	0.00 %
Calcium deficiency	Metabolism and nutrition disorders	2	0.00 %
Calcium embolism	Vascular disorders	2	0.00 %
Calcium ionised increased	Investigations	2	0.00 %
Capsular contracture associated with implant	General disorders and administration site conditions	2	0.00 %
Carbuncle	Infections and infestations	2	0.00 %
Cardiac ablation	Surgical and medical procedures	2	0.00 %
Cardiac murmur functional	Investigations	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Cardiac neoplasm unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Cardiac septal defect	Congenital, familial and genetic disorders	2	0.00 %
Cardiolipin antibody	Investigations	2	0.00 %
Cardiomyopathy acute	Cardiac disorders	2	0.00 %
Cardiomyopathy neonatal	Cardiac disorders	2	0.00 %
Cardiopulmonary exercise test abnormal	Investigations	2	0.00 %
Caregiver	Social circumstances	2	0.00 %
Carotid intima-media thickness increased	Investigations	2	0.00 %
Cataract congenital	Congenital, familial and genetic disorders	2	0.00 %
Catastrophic reaction	Psychiatric disorders	2	0.00 %
Catheter site haemorrhage	General disorders and administration site conditions	2	0.00 %
Catheter site infection	Infections and infestations	2	0.00 %
Catheter site injury	General disorders and administration site conditions	2	0.00 %
Catheter site thrombosis	General disorders and administration site conditions	2	0.00 %
Cellulitis gangrenous	Infections and infestations	2	0.00 %
Central nervous system viral infection	Infections and infestations	2	0.00 %
Central obesity	Metabolism and nutrition disorders	2	0.00 %
Central venous pressure abnormal	Investigations	2	0.00 %
Cephalhaematoma	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Cerebellar artery occlusion	Nervous system disorders	2	0.00 %
Cerebral artery perforation	Nervous system disorders	2	0.00 %
Cerebral capillary telangiectasia	Nervous system disorders	2	0.00 %
Cerebral circulatory failure	Nervous system disorders	2	0.00 %
Cerebral haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Cerebral haemorrhage neonatal	Nervous system disorders	2	0.00 %
Cerebral salt-wasting syndrome	Metabolism and nutrition disorders	2	0.00 %
Cerebral vasodilatation	Nervous system disorders	2	0.00 %
Cervical cyst	Reproductive system and breast disorders	2	0.00 %
Cervical friability	Reproductive system and breast disorders	2	0.00 %
Cervix oedema	Reproductive system and breast disorders	2	0.00 %
Challenge site reaction	General disorders and administration site conditions	2	0.00 %
Change in seizure presentation	Nervous system disorders	2	0.00 %
Change in sustained attention	Psychiatric disorders	2	0.00 %
Chemical cystitis	Injury, poisoning and procedural complications	2	0.00 %
Chemokine increased	Investigations	2	0.00 %
Chemotherapy	Surgical and medical procedures	2	0.00 %
Chest expansion decreased	Investigations	2	0.00 %
Childhood asthma	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Chondromalacia	Musculoskeletal and connective tissue disorders	2	0.00 %
Chondromatoses	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Chordee	Congenital, familial and genetic disorders	2	0.00 %
Chorioretinal atrophy	Eye disorders	2	0.00 %
Choroidal rupture	Eye disorders	2	0.00 %
Chronic active Epstein-Barr virus infection	Infections and infestations	2	0.00 %
Chronic graft versus host disease	Immune system disorders	2	0.00 %
Chronic hepatic failure	Hepatobiliary disorders	2	0.00 %
Chronic myelomonocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Ciliary muscle spasm	Eye disorders	2	0.00 %
Cirrhosis alcoholic	Hepatobiliary disorders	2	0.00 %
Cleft palate	Congenital, familial and genetic disorders	2	0.00 %
Clinodactyly	Congenital, familial and genetic disorders	2	0.00 %
Clitoral engorgement	Reproductive system and breast disorders	2	0.00 %
CNS ventriculitis	Infections and infestations	2	0.00 %
Coagulation time abnormal	Investigations	2	0.00 %
Cogan's syndrome	Eye disorders	2	0.00 %
Cold agglutinins	Investigations	2	0.00 %
Cold shock response	Injury, poisoning and procedural complications	2	0.00 %
Colon cancer stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Colorectal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Combined immunodeficiency	Congenital, familial and genetic disorders	2	0.00 %
Comminuted fracture	Injury, poisoning and procedural complications	2	0.00 %
Community acquired infection	Infections and infestations	2	0.00 %
Complication of device removal	General disorders and administration site conditions	2	0.00 %
Complications of transplanted kidney	Injury, poisoning and procedural complications	2	0.00 %
Computer vision syndrome	Eye disorders	2	0.00 %
Computerised tomogram head	Investigations	2	0.00 %
Computerised tomogram pancreas abnormal	Investigations	2	0.00 %
Concentric sclerosis	Nervous system disorders	2	0.00 %
Confusional arousal	Psychiatric disorders	2	0.00 %
Congenital absence of cranial vault	Congenital, familial and genetic disorders	2	0.00 %
Congenital great vessel anomaly	Congenital, familial and genetic disorders	2	0.00 %
Congenital hearing disorder	Congenital, familial and genetic disorders	2	0.00 %
Congenital heart valve disorder	Congenital, familial and genetic disorders	2	0.00 %
Congenital LUMBAR syndrome	Congenital, familial and genetic disorders	2	0.00 %
Congenital musculoskeletal anomaly	Congenital, familial and genetic disorders	2	0.00 %
Conjunctival adhesion	Eye disorders	2	0.00 %
Conjunctival staining	Investigations	2	0.00 %
Conjunctival ulcer	Eye disorders	2	0.00 %
Contraception	Surgical and medical procedures	2	0.00 %
Contraceptive implant	Surgical and medical procedures	2	0.00 %
Contraindication to medical treatment	Social circumstances	2	0.00 %
Conus medullaris syndrome	Nervous system disorders	2	0.00 %
Convulsion in childhood	Nervous system disorders	2	0.00 %
Coprolalia	Psychiatric disorders	2	0.00 %
Cor pulmonale chronic	Cardiac disorders	2	0.00 %
Corneal degeneration	Eye disorders	2	0.00 %
Corneal endotheliitis	Eye disorders	2	0.00 %
Coronary arterial stent insertion	Surgical and medical procedures	2	0.00 %
Corrective lens user	Social circumstances	2	0.00 %
Cortical dysplasia	Congenital, familial and genetic disorders	2	0.00 %
Coxiella test positive	Investigations	2	0.00 %
Craniosynostosis	Congenital, familial and genetic disorders	2	0.00 %
Creatine urine increased	Investigations	2	0.00 %
Creatinine renal clearance abnormal	Investigations	2	0.00 %
Creatinine renal clearance increased	Investigations	2	0.00 %
Creatinine urine decreased	Investigations	2	0.00 %
Creatinine urine increased	Investigations	2	0.00 %
Crush syndrome	Renal and urinary disorders	2	0.00 %
Cryopyrin associated periodic syndrome	Congenital, familial and genetic disorders	2	0.00 %
Cryptorchism	Congenital, familial and genetic disorders	2	0.00 %
Cryptosporidiosis infection	Infections and infestations	2	0.00 %
Crystal urine	Investigations	2	0.00 %
CSF culture positive	Investigations	2	0.00 %
CSF glucose decreased	Investigations	2	0.00 %
CSF lactate increased	Investigations	2	0.00 %
CSF polymorphonuclear cell count increased	Investigations	2	0.00 %
CSF pressure abnormal	Investigations	2	0.00 %
CSF protein abnormal	Investigations	2	0.00 %
CT hypotension complex	Vascular disorders	2	0.00 %
Cystitis glandularis	Renal and urinary disorders	2	0.00 %
Cystitis klebsiella	Infections and infestations	2	0.00 %
Cytokine abnormal	Investigations	2	0.00 %
Cytomegalovirus mononucleosis	Infections and infestations	2	0.00 %
Cytomegalovirus viraemia	Infections and infestations	2	0.00 %
Dacryocanaliculitis	Infections and infestations	2	0.00 %
Dacryostenosis congenital	Congenital, familial and genetic disorders	2	0.00 %
Deafness permanent	Ear and labyrinth disorders	2	0.00 %
Decorticate posture	Nervous system disorders	2	0.00 %
Decreased embryo viability	Injury, poisoning and procedural complications	2	0.00 %
Deficiency anaemia	Blood and lymphatic system disorders	2	0.00 %
Degenerative aortic valve disease	Cardiac disorders	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Dehydroepiandrosterone increased	Investigations	2	0.00 %
Delusional disorder, persecutory type	Psychiatric disorders	2	0.00 %
Dementia of the Alzheimer's type, with delirium	Nervous system disorders	2	0.00 %
Dementia with Lewy bodies	Nervous system disorders	2	0.00 %
Dental care	Surgical and medical procedures	2	0.00 %
Dental fistula	Infections and infestations	2	0.00 %
Dental implantation	Surgical and medical procedures	2	0.00 %
Dental leakage	Injury, poisoning and procedural complications	2	0.00 %
Dental plaque	Gastrointestinal disorders	2	0.00 %
Dental pulp disorder	Gastrointestinal disorders	2	0.00 %
Dependence	Psychiatric disorders	2	0.00 %
Dermatologic examination abnormal	Investigations	2	0.00 %
Detachment of retinal pigment epithelium	Eye disorders	2	0.00 %
Device leakage	Product issues	2	0.00 %
Device use confusion	Injury, poisoning and procedural complications	2	0.00 %
Device use issue	Injury, poisoning and procedural complications	2	0.00 %
Diabetic foot infection	Infections and infestations	2	0.00 %
Diabetic retinopathy	Eye disorders	2	0.00 %
Dialysis	Surgical and medical procedures	2	0.00 %
Dialysis related complication	Injury, poisoning and procedural complications	2	0.00 %
Dientamoeba infection	Infections and infestations	2	0.00 %
Differential white blood cell count	Investigations	2	0.00 %
Diffuse axonal injury	Injury, poisoning and procedural complications	2	0.00 %
Digital pulpitis	Skin and subcutaneous tissue disorders	2	0.00 %
Diphtheria	Infections and infestations	2	0.00 %
Disability assessment scale score increased	Investigations	2	0.00 %
Disease risk factor	Social circumstances	2	0.00 %
Dislocation of vertebra	Injury, poisoning and procedural complications	2	0.00 %
Disseminated intravascular coagulation in newborn	Blood and lymphatic system disorders	2	0.00 %
Diverticulitis intestinal perforated	Infections and infestations	2	0.00 %
Dolichocolon	Congenital, familial and genetic disorders	2	0.00 %
Double stranded DNA antibody positive	Investigations	2	0.00 %
Drug abuse	Psychiatric disorders	2	0.00 %
Drug dependence	Psychiatric disorders	2	0.00 %
Drug specific antibody	Investigations	2	0.00 %
Drug tolerance	General disorders and administration site conditions	2	0.00 %
Drug-disease interaction	General disorders and administration site conditions	2	0.00 %
Dry gangrene	Vascular disorders	2	0.00 %
Ductus arteriosus premature closure	Congenital, familial and genetic disorders	2	0.00 %
Dyskinesia oesophageal	Gastrointestinal disorders	2	0.00 %
Dysmetropsia	Eye disorders	2	0.00 %
Ear canal injury	Injury, poisoning and procedural complications	2	0.00 %
Ear canal stenosis	Ear and labyrinth disorders	2	0.00 %
Ear infection viral	Infections and infestations	2	0.00 %
Ear lobe infection	Infections and infestations	2	0.00 %
Ear, nose and throat disorder	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Early repolarisation syndrome	Cardiac disorders	2	0.00 %
Eastern Cooperative Oncology Group performance status worsened	Investigations	2	0.00 %
ECG P wave inverted	Investigations	2	0.00 %
Ecthyma	Infections and infestations	2	0.00 %
Electrocardiogram ambulatory	Investigations	2	0.00 %
Electrocardiogram P wave abnormal	Investigations	2	0.00 %
Electrocardiogram PR segment elevation	Investigations	2	0.00 %
Electrocardiogram ST-T segment depression	Investigations	2	0.00 %
Electrolyte substitution therapy	Surgical and medical procedures	2	0.00 %
Elliptocytosis	Blood and lymphatic system disorders	2	0.00 %
Embedded device	Product issues	2	0.00 %
Embolia cutis medicamentosa	General disorders and administration site conditions	2	0.00 %
Emergency care	Surgical and medical procedures	2	0.00 %
Encephalitis meningococcal	Infections and infestations	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Encopresis	Psychiatric disorders	2	0.00 %
Endocardial fibrosis	Cardiac disorders	2	0.00 %
Endocarditis staphylococcal	Infections and infestations	2	0.00 %
Enterobiasis	Infections and infestations	2	0.00 %
Enterocutaneous fistula	Gastrointestinal disorders	2	0.00 %
Enzyme level abnormal	Investigations	2	0.00 %
Eosinopenia	Blood and lymphatic system disorders	2	0.00 %
Eosinophil count	Investigations	2	0.00 %
Eosinophilic bronchitis	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Eosinophilic colitis	Gastrointestinal disorders	2	0.00 %
Eosinophilic pneumonia chronic	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Epithelioid sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Epstein-Barr virus antibody	Investigations	2	0.00 %
Erythema elevatum diutinum	Skin and subcutaneous tissue disorders	2	0.00 %
Erythema marginatum	Skin and subcutaneous tissue disorders	2	0.00 %
Erythematotelangiectatic rosacea	Skin and subcutaneous tissue disorders	2	0.00 %
Erythropoiesis abnormal	Blood and lymphatic system disorders	2	0.00 %
Eustachian tube patulous	Ear and labyrinth disorders	2	0.00 %
Euthyroid sick syndrome	Endocrine disorders	2	0.00 %
Ex-tobacco user	Social circumstances	2	0.00 %
Excessive exercise	Social circumstances	2	0.00 %
Exposure keratitis	Eye disorders	2	0.00 %
Exposure to allergen	Injury, poisoning and procedural complications	2	0.00 %
Exposure to contaminated water	Injury, poisoning and procedural complications	2	0.00 %
Exposure to extreme temperature	Injury, poisoning and procedural complications	2	0.00 %
Exsanguination	Vascular disorders	2	0.00 %
External compression headache	Nervous system disorders	2	0.00 %
Eye complication associated with device	General disorders and administration site conditions	2	0.00 %
Eye infection bacterial	Infections and infestations	2	0.00 %
Eye infection intraocular	Infections and infestations	2	0.00 %
Eye infection toxoplasmal	Infections and infestations	2	0.00 %
Eye irrigation	Surgical and medical procedures	2	0.00 %
Eye opacity	Eye disorders	2	0.00 %
Eyelash changes	Eye disorders	2	0.00 %
Eyelid boil	Infections and infestations	2	0.00 %
Faciobrachial dystonic seizure	Nervous system disorders	2	0.00 %
Factor VIII inhibition	Blood and lymphatic system disorders	2	0.00 %
Factor X deficiency	Congenital, familial and genetic disorders	2	0.00 %
Faecal calprotectin decreased	Investigations	2	0.00 %
Faecalith	Gastrointestinal disorders	2	0.00 %
False labour	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Familial amyotrophic lateral sclerosis	Congenital, familial and genetic disorders	2	0.00 %
Familial hemiplegic migraine	Congenital, familial and genetic disorders	2	0.00 %
Familial tremor	Congenital, familial and genetic disorders	2	0.00 %
Fasciolopsiasis	Infections and infestations	2	0.00 %
Feeding tube user	Social circumstances	2	0.00 %
Female genital tract fistula	Reproductive system and breast disorders	2	0.00 %
Female sex hormone level	Investigations	2	0.00 %
Fertility increased	Endocrine disorders	2	0.00 %
Fibrin abnormal	Investigations	2	0.00 %
Fibrin D dimer normal	Investigations	2	0.00 %
Fibrinogen degradation products increased	Investigations	2	0.00 %
Fibrinolysis	Investigations	2	0.00 %
Fibrinolysis increased	Investigations	2	0.00 %
Fine motor delay	Nervous system disorders	2	0.00 %
Fingerprint loss	Skin and subcutaneous tissue disorders	2	0.00 %
Flail chest	Injury, poisoning and procedural complications	2	0.00 %
Floppy eyelid syndrome	Eye disorders	2	0.00 %
Focal myositis	Musculoskeletal and connective tissue disorders	2	0.00 %
Focal nodular hyperplasia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Foetal heart rate deceleration abnormality	Cardiac disorders	2	0.00 %
Foetal heart rate increased	Investigations	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Foetal macrosomia	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Foetal monitoring abnormal	Investigations	2	0.00 %
Foot and mouth disease	Infections and infestations	2	0.00 %
Forearm fracture	Injury, poisoning and procedural complications	2	0.00 %
Foreign body in gastrointestinal tract	Injury, poisoning and procedural complications	2	0.00 %
Foreign body in skin or subcutaneous tissue	Injury, poisoning and procedural complications	2	0.00 %
Fournier's gangrene	Infections and infestations	2	0.00 %
Fracture displacement	Injury, poisoning and procedural complications	2	0.00 %
Fractured coccyx	Injury, poisoning and procedural complications	2	0.00 %
Fractured sacrum	Injury, poisoning and procedural complications	2	0.00 %
Frontal sinus operation	Surgical and medical procedures	2	0.00 %
Frontotemporal dementia	Nervous system disorders	2	0.00 %
Functional residual capacity decreased	Investigations	2	0.00 %
Fungaemia	Infections and infestations	2	0.00 %
Fungal oesophagitis	Infections and infestations	2	0.00 %
Gallbladder cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Gallbladder operation	Surgical and medical procedures	2	0.00 %
Gasping syndrome	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Gastric adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Gastric cancer stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Gastric mucosa erythema	Gastrointestinal disorders	2	0.00 %
Gastric mucosal lesion	Gastrointestinal disorders	2	0.00 %
Gastric volvulus	Gastrointestinal disorders	2	0.00 %
Gastroenteritis rotavirus	Infections and infestations	2	0.00 %
Gastrointestinal bacterial infection	Infections and infestations	2	0.00 %
Gastrointestinal candidiasis	Infections and infestations	2	0.00 %
Gastrointestinal fungal infection	Infections and infestations	2	0.00 %
Gastrointestinal lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Gastrointestinal mucosa hyperaemia	Gastrointestinal disorders	2	0.00 %
Gastrointestinal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Gastrointestinal somatic symptom disorder	Psychiatric disorders	2	0.00 %
Gastrointestinal toxicity	Gastrointestinal disorders	2	0.00 %
Gastrooesophageal sphincter insufficiency	Gastrointestinal disorders	2	0.00 %
General physical condition	Investigations	2	0.00 %
Generalised bullous fixed drug eruption	Skin and subcutaneous tissue disorders	2	0.00 %
Genital discolouration	Reproductive system and breast disorders	2	0.00 %
Genital disorder	Reproductive system and breast disorders	2	0.00 %
Genital exfoliation	Reproductive system and breast disorders	2	0.00 %
Genital hyperaesthesia	Reproductive system and breast disorders	2	0.00 %
Genital injury	Injury, poisoning and procedural complications	2	0.00 %
Genital odour	Reproductive system and breast disorders	2	0.00 %
Genital ulcer syndrome	Infections and infestations	2	0.00 %
Genitals enlarged	Reproductive system and breast disorders	2	0.00 %
Gingival atrophy	Gastrointestinal disorders	2	0.00 %
Gingival erosion	Gastrointestinal disorders	2	0.00 %
Glaucomatocyclitic crises	Eye disorders	2	0.00 %
Glial scar	Nervous system disorders	2	0.00 %
Glioblastoma multiforme	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Glomerulonephropathy	Renal and urinary disorders	2	0.00 %
Glomerulosclerosis	Renal and urinary disorders	2	0.00 %
Glutamate dehydrogenase increased	Investigations	2	0.00 %
Glycosylated haemoglobin decreased	Investigations	2	0.00 %
Granulocytes abnormal	Investigations	2	0.00 %
Granulomatous lymphadenitis	Blood and lymphatic system disorders	2	0.00 %
Grimacing	Nervous system disorders	2	0.00 %
Growth failure	Musculoskeletal and connective tissue disorders	2	0.00 %
Growth hormone deficiency	Endocrine disorders	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Gynaecological examination	Investigations	2	0.00 %
Gynaecological examination normal	Investigations	2	0.00 %
H3N2 influenza	Infections and infestations	2	0.00 %
Haemangioma of breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Haemangioma of spleen	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Haematopoietic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Haemoconcentration	Blood and lymphatic system disorders	2	0.00 %
Haemodialysis	Surgical and medical procedures	2	0.00 %
Haemoglobin urine	Investigations	2	0.00 %
Haemophilic arthropathy	Musculoskeletal and connective tissue disorders	2	0.00 %
Haemorrhage coronary artery	Cardiac disorders	2	0.00 %
Haemorrhage subepidermal	Skin and subcutaneous tissue disorders	2	0.00 %
Haemorrhagic breast cyst	Reproductive system and breast disorders	2	0.00 %
Haemorrhagic thyroid cyst	Endocrine disorders	2	0.00 %
Haemorrhagic vasculitis	Vascular disorders	2	0.00 %
Haemosiderin stain	Skin and subcutaneous tissue disorders	2	0.00 %
Hair dye user	Social circumstances	2	0.00 %
Hallucination, gustatory	Psychiatric disorders	2	0.00 %
Hamartoma	Congenital, familial and genetic disorders	2	0.00 %
Hashitoxicosis	Immune system disorders	2	0.00 %
Head circumference abnormal	Investigations	2	0.00 %
Heart transplant rejection	Immune system disorders	2	0.00 %
Heart valve operation	Surgical and medical procedures	2	0.00 %
Helminthic infection	Infections and infestations	2	0.00 %
Hemianopia heteronymous	Nervous system disorders	2	0.00 %
Hepatic adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Hepatic cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Hepatic cyst infection	Infections and infestations	2	0.00 %
Hepatic enzyme decreased	Investigations	2	0.00 %
Hepatic hypertrophy	Hepatobiliary disorders	2	0.00 %
Hepatic perfusion disorder	Hepatobiliary disorders	2	0.00 %
Hepatitis A virus test positive	Investigations	2	0.00 %
Hepatitis alcoholic	Hepatobiliary disorders	2	0.00 %
Hepatitis B surface antigen positive	Investigations	2	0.00 %
Hepatitis C virus test positive	Investigations	2	0.00 %
Hereditary fructose intolerance	Congenital, familial and genetic disorders	2	0.00 %
Hereditary spherocytosis	Congenital, familial and genetic disorders	2	0.00 %
Herpes sepsis	Infections and infestations	2	0.00 %
Herpes simplex otitis externa	Infections and infestations	2	0.00 %
Herpes zoster pharyngitis	Infections and infestations	2	0.00 %
Herpetic radiculopathy	Infections and infestations	2	0.00 %
Heterotaxia	Congenital, familial and genetic disorders	2	0.00 %
High density lipoprotein abnormal	Investigations	2	0.00 %
Hip deformity	Musculoskeletal and connective tissue disorders	2	0.00 %
Homicidal ideation	Psychiatric disorders	2	0.00 %
Hookworm infection	Infections and infestations	2	0.00 %
Hormone replacement therapy	Surgical and medical procedures	2	0.00 %
Human chorionic gonadotropin positive	Investigations	2	0.00 %
Human epidermal growth factor receptor increased	Investigations	2	0.00 %
Human herpesvirus 6 infection reactivation	Infections and infestations	2	0.00 %
Human rhinovirus test positive	Investigations	2	0.00 %
Hydrophobia	Psychiatric disorders	2	0.00 %
Hyperaldosteronism	Endocrine disorders	2	0.00 %
Hyperamylasaemia	Metabolism and nutrition disorders	2	0.00 %
Hyperarousal	Psychiatric disorders	2	0.00 %
Hyperbilirubinaemia neonatal	Hepatobiliary disorders	2	0.00 %
Hyperdynamic left ventricle	Cardiac disorders	2	0.00 %
Hyperintensity in brain deep nuclei	Nervous system disorders	2	0.00 %
Hyperkinetic heart syndrome	Cardiac disorders	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Hyperphosphataemia	Metabolism and nutrition disorders	2	0.00 %
Hypersomnia-bulimia syndrome	Psychiatric disorders	2	0.00 %
Hypertensive angiopathy	Vascular disorders	2	0.00 %
Hypertensive nephropathy	Renal and urinary disorders	2	0.00 %
Hypervitaminosis B12	Metabolism and nutrition disorders	2	0.00 %
Hypocholesterolaemia	Metabolism and nutrition disorders	2	0.00 %
Hypofibrinogenaemia	Blood and lymphatic system disorders	2	0.00 %
Hypoglycaemia unawareness	Metabolism and nutrition disorders	2	0.00 %
Hypoparathyroidism	Endocrine disorders	2	0.00 %
Hypoplastic anaemia	Blood and lymphatic system disorders	2	0.00 %
Hypospadias	Congenital, familial and genetic disorders	2	0.00 %
Hypothyroidic goitre	Endocrine disorders	2	0.00 %
Hypotonic urinary bladder	Renal and urinary disorders	2	0.00 %
Iatrogenic infection	Infections and infestations	2	0.00 %
Idiopathic generalised epilepsy	Nervous system disorders	2	0.00 %
IIIrd nerve injury	Injury, poisoning and procedural complications	2	0.00 %
Ileal gangrene	Infections and infestations	2	0.00 %
Imaging procedure abnormal	Investigations	2	0.00 %
Immobilisation prolonged	Social circumstances	2	0.00 %
Immune tolerance induction	Surgical and medical procedures	2	0.00 %
Immune-mediated myocarditis	Cardiac disorders	2	0.00 %
Immunoglobulins	Investigations	2	0.00 %
Immunoglobulins decreased	Investigations	2	0.00 %
Impaired insulin secretion	Metabolism and nutrition disorders	2	0.00 %
Implant site discolouration	General disorders and administration site conditions	2	0.00 %
Implant site infection	Infections and infestations	2	0.00 %
Implant site nodule	General disorders and administration site conditions	2	0.00 %
Implant site pruritus	General disorders and administration site conditions	2	0.00 %
Implantable defibrillator insertion	Surgical and medical procedures	2	0.00 %
Implantation complication	Injury, poisoning and procedural complications	2	0.00 %
Inadequate diet	Social circumstances	2	0.00 %
Incarcerated hernia	General disorders and administration site conditions	2	0.00 %
Incision site complication	Injury, poisoning and procedural complications	2	0.00 %
Incision site rash	Injury, poisoning and procedural complications	2	0.00 %
Incisional hernia	Injury, poisoning and procedural complications	2	0.00 %
Incorrect dose administered by device	Injury, poisoning and procedural complications	2	0.00 %
Incorrect drug administration rate	Injury, poisoning and procedural complications	2	0.00 %
Infant sedation	Nervous system disorders	2	0.00 %
Infantile colic	Gastrointestinal disorders	2	0.00 %
Infected lymphocele	Infections and infestations	2	0.00 %
Infectious disease carrier	Infections and infestations	2	0.00 %
Infective exacerbation of bronchiectasis	Infections and infestations	2	0.00 %
Infective myositis	Infections and infestations	2	0.00 %
Inferior vena cava syndrome	Vascular disorders	2	0.00 %
Infertility male	Reproductive system and breast disorders	2	0.00 %
Infestation	Infections and infestations	2	0.00 %
Inflammation of lacrimal passage	Eye disorders	2	0.00 %
Infrapatellar fat pad inflammation	Musculoskeletal and connective tissue disorders	2	0.00 %
Infusion site joint inflammation	General disorders and administration site conditions	2	0.00 %
Infusion site joint pain	General disorders and administration site conditions	2	0.00 %
Injection site coldness	General disorders and administration site conditions	2	0.00 %
Injection site granuloma	General disorders and administration site conditions	2	0.00 %
Injection site hyperesthesia	General disorders and administration site conditions	2	0.00 %
Injection site joint erythema	General disorders and administration site conditions	2	0.00 %
Injection site joint warmth	General disorders and administration site conditions	2	0.00 %
Injection site macule	General disorders and administration site conditions	2	0.00 %
Injection site necrosis	General disorders and administration site conditions	2	0.00 %
Injection site nerve damage	General disorders and administration site conditions	2	0.00 %
Injection site scab	General disorders and administration site conditions	2	0.00 %
Injection site ulcer	General disorders and administration site conditions	2	0.00 %
Instillation site pain	General disorders and administration site conditions	2	0.00 %
Insulin resistant diabetes	Metabolism and nutrition disorders	2	0.00 %
Intentional underdose	Injury, poisoning and procedural complications	2	0.00 %
Intercepted product preparation error	Injury, poisoning and procedural complications	2	0.00 %
Interferon beta level increased	Investigations	2	0.00 %
Interleukin level decreased	Investigations	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Interstitial granulomatous dermatitis	Skin and subcutaneous tissue disorders	2	0.00 %
Intestinal congestion	Gastrointestinal disorders	2	0.00 %
Intestinal polyp	Gastrointestinal disorders	2	0.00 %
Intestinal resection	Surgical and medical procedures	2	0.00 %
Intestinal transit time abnormal	Investigations	2	0.00 %
Intra-abdominal haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Intra-uterine contraceptive device insertion	Surgical and medical procedures	2	0.00 %
Intracranial artery dissection	Nervous system disorders	2	0.00 %
Intraductal papillary mucinous neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Intraductal proliferative breast lesion	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Intrapericardial thrombosis	Cardiac disorders	2	0.00 %
Intravascular haemolysis	Blood and lymphatic system disorders	2	0.00 %
Invasive lobular breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Iris adhesions	Eye disorders	2	0.00 %
Iris discolouration	Eye disorders	2	0.00 %
Iron binding capacity unsaturated increased	Investigations	2	0.00 %
Ischaemic contracture of the left ventricle	Injury, poisoning and procedural complications	2	0.00 %
Ischaemic neuropathy	Nervous system disorders	2	0.00 %
Ischaemic skin ulcer	Skin and subcutaneous tissue disorders	2	0.00 %
Janus kinase 2 mutation	Congenital, familial and genetic disorders	2	0.00 %
Jarisch-Herxheimer reaction	Immune system disorders	2	0.00 %
Jaundice acholuric	Blood and lymphatic system disorders	2	0.00 %
Jaw operation	Surgical and medical procedures	2	0.00 %
Joint abscess	Infections and infestations	2	0.00 %
Joint adhesion	Musculoskeletal and connective tissue disorders	2	0.00 %
Joint arthroplasty	Surgical and medical procedures	2	0.00 %
Joint deposit	Musculoskeletal and connective tissue disorders	2	0.00 %
Joint microhaemorrhage	Musculoskeletal and connective tissue disorders	2	0.00 %
Joint prosthesis user	Social circumstances	2	0.00 %
Juvenile myoclonic epilepsy	Nervous system disorders	2	0.00 %
Keratitis viral	Infections and infestations	2	0.00 %
Keratoacanthoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Keratolysis exfoliativa acquired	Skin and subcutaneous tissue disorders	2	0.00 %
Kidney duplex	Congenital, familial and genetic disorders	2	0.00 %
Kidney fibrosis	Renal and urinary disorders	2	0.00 %
Kidney rupture	Injury, poisoning and procedural complications	2	0.00 %
Kidney small	Renal and urinary disorders	2	0.00 %
KL-6 increased	Investigations	2	0.00 %
Klebsiella bacteraemia	Infections and infestations	2	0.00 %
Klebsiella sepsis	Infections and infestations	2	0.00 %
Kyphoscoliosis	Musculoskeletal and connective tissue disorders	2	0.00 %
Laboratory test interference	Investigations	2	0.00 %
Lack of satiety	Metabolism and nutrition disorders	2	0.00 %
Lactation inhibition therapy	Surgical and medical procedures	2	0.00 %
Large intestinal stenosis	Gastrointestinal disorders	2	0.00 %
Large intestinal ulcer haemorrhage	Gastrointestinal disorders	2	0.00 %
Laryngeal haematoma	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Laryngeal haemorrhage	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Laryngeal mass	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Laryngitis viral	Infections and infestations	2	0.00 %
Laryngomalacia	Congenital, familial and genetic disorders	2	0.00 %
Lasegue's test positive	Investigations	2	0.00 %
LE cells present	Investigations	2	0.00 %
Legionella test positive	Investigations	2	0.00 %
Leucine aminopeptidase increased	Investigations	2	0.00 %
Leukoderma	Skin and subcutaneous tissue disorders	2	0.00 %
Lewis-Sumner syndrome	Nervous system disorders	2	0.00 %
Lice infestation	Infections and infestations	2	0.00 %
Limb amputation	Surgical and medical procedures	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Limb girth decreased	Investigations	2	0.00 %
Limb prosthesis user	Social circumstances	2	0.00 %
Limb reduction defect	Congenital, familial and genetic disorders	2	0.00 %
Linear IgA disease	Skin and subcutaneous tissue disorders	2	0.00 %
Lip haematoma	Gastrointestinal disorders	2	0.00 %
Lip scab	Gastrointestinal disorders	2	0.00 %
Lipid metabolism disorder	Metabolism and nutrition disorders	2	0.00 %
Lipohypertrophy	Skin and subcutaneous tissue disorders	2	0.00 %
Lipomatosis	Metabolism and nutrition disorders	2	0.00 %
Listeria test positive	Investigations	2	0.00 %
Living alone	Social circumstances	2	0.00 %
Lobular breast carcinoma in situ	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Locomotive syndrome	Musculoskeletal and connective tissue disorders	2	0.00 %
Loss of therapeutic response	General disorders and administration site conditions	2	0.00 %
Loss of visual contrast sensitivity	Eye disorders	2	0.00 %
Ludwig angina	Infections and infestations	2	0.00 %
Lumbar hernia	Gastrointestinal disorders	2	0.00 %
Lumbosacral plexus injury	Injury, poisoning and procedural complications	2	0.00 %
Lung assist device therapy	Surgical and medical procedures	2	0.00 %
Lung carcinoma cell type unspecified stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Lupus vasculitis	Vascular disorders	2	0.00 %
Lymph node fibrosis	Blood and lymphatic system disorders	2	0.00 %
Lymph node tuberculosis	Infections and infestations	2	0.00 %
Lymphadenitis viral	Infections and infestations	2	0.00 %
Lymphocyte stimulation test positive	Investigations	2	0.00 %
Macrophage activation	Surgical and medical procedures	2	0.00 %
Macular rupture	Eye disorders	2	0.00 %
MAGIC syndrome	Vascular disorders	2	0.00 %
Magnesium deficiency	Metabolism and nutrition disorders	2	0.00 %
Malaria recrudescence	Infections and infestations	2	0.00 %
Malignant nervous system neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Mantle cell lymphoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Marrow hyperplasia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Mast cell degranulation present	Investigations	2	0.00 %
Mastoptosis	Reproductive system and breast disorders	2	0.00 %
Maximal voluntary ventilation	Investigations	2	0.00 %
Mean cell haemoglobin concentration abnormal	Investigations	2	0.00 %
Measles post vaccine	Infections and infestations	2	0.00 %
Meconium peritonitis	Gastrointestinal disorders	2	0.00 %
Meconium stain	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Mediastinitis	Infections and infestations	2	0.00 %
Medical device discomfort	General disorders and administration site conditions	2	0.00 %
Medical device site joint swelling	General disorders and administration site conditions	2	0.00 %
Medical device site movement impairment	General disorders and administration site conditions	2	0.00 %
Medical device site rash	General disorders and administration site conditions	2	0.00 %
Medical procedure	Surgical and medical procedures	2	0.00 %
Meibomianitis	Eye disorders	2	0.00 %
Melanoderma	Skin and subcutaneous tissue disorders	2	0.00 %
Meningioma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Meningitis coxsackie viral	Infections and infestations	2	0.00 %
Meningitis noninfective	Nervous system disorders	2	0.00 %
Meningitis tuberculous	Infections and infestations	2	0.00 %
Meningococcal infection	Infections and infestations	2	0.00 %
Meningomyelitis herpes	Infections and infestations	2	0.00 %
Mental disorder due to a general medical condition	Psychiatric disorders	2	0.00 %
Merycism	Psychiatric disorders	2	0.00 %
Mesenteric artery aneurysm	Gastrointestinal disorders	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Mesenteric haemorrhage	Gastrointestinal disorders	2	0.00 %
Mesothelioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Metamyelocyte percentage increased	Investigations	2	0.00 %
Metastases to meninges	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Metastases to spleen	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Metastases to the mediastinum	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Metastatic bronchial carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Meteoropathy	General disorders and administration site conditions	2	0.00 %
Micrographia	Nervous system disorders	2	0.00 %
Microvascular cranial nerve palsy	Nervous system disorders	2	0.00 %
Middle lobe syndrome	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Migraine prophylaxis	Surgical and medical procedures	2	0.00 %
Mitochondrial cytopathy	Metabolism and nutrition disorders	2	0.00 %
Mitochondrial myopathy	Congenital, familial and genetic disorders	2	0.00 %
Mitral valve atresia	Congenital, familial and genetic disorders	2	0.00 %
Mitral valve repair	Surgical and medical procedures	2	0.00 %
Mitral valve thickening	Cardiac disorders	2	0.00 %
Monoblast count decreased	Investigations	2	0.00 %
Monoblast count increased	Investigations	2	0.00 %
Monoclonal B-cell lymphocytosis	Blood and lymphatic system disorders	2	0.00 %
Monocyte percentage abnormal	Investigations	2	0.00 %
Monocyte percentage decreased	Investigations	2	0.00 %
Mood disorder due to a general medical condition	Psychiatric disorders	2	0.00 %
Motor developmental delay	Nervous system disorders	2	0.00 %
Mucocutaneous disorder	Skin and subcutaneous tissue disorders	2	0.00 %
Multiparous	Social circumstances	2	0.00 %
Multiple chemical sensitivity	Immune system disorders	2	0.00 %
Multiple congenital abnormalities	Congenital, familial and genetic disorders	2	0.00 %
Multiple system atrophy	Nervous system disorders	2	0.00 %
Muscle fibrosis	Musculoskeletal and connective tissue disorders	2	0.00 %
Muscle hernia	Injury, poisoning and procedural complications	2	0.00 %
Muscle infarction	Musculoskeletal and connective tissue disorders	2	0.00 %
Myocardial haemorrhage	Cardiac disorders	2	0.00 %
Myocarditis mycotic	Infections and infestations	2	0.00 %
Myocarditis post infection	Cardiac disorders	2	0.00 %
Myofascial spasm	Musculoskeletal and connective tissue disorders	2	0.00 %
Nail avulsion	Injury, poisoning and procedural complications	2	0.00 %
Nail bed infection	Infections and infestations	2	0.00 %
Nail bed tenderness	Skin and subcutaneous tissue disorders	2	0.00 %
Nail dystrophy	Skin and subcutaneous tissue disorders	2	0.00 %
Nasal mucosal blistering	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Nasal mucosal erosion	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Nasal mucosal ulcer	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Needle fatigue	Injury, poisoning and procedural complications	2	0.00 %
Negativism	Psychiatric disorders	2	0.00 %
Neglect of personal appearance	Psychiatric disorders	2	0.00 %
Neonatal anoxia	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Neonatal infection	Infections and infestations	2	0.00 %
Neonatal tachypnoea	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Nephropathy toxic	Renal and urinary disorders	2	0.00 %
Neurofibroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Neurogenic bowel	Gastrointestinal disorders	2	0.00 %
Neurologic somatic symptom disorder	Psychiatric disorders	2	0.00 %
Neurone-specific enolase increased	Investigations	2	0.00 %
NIH stroke scale score decreased	Investigations	2	0.00 %
Nipple enlargement	Reproductive system and breast disorders	2	0.00 %
Nipple oedema	Reproductive system and breast disorders	2	0.00 %
Non-alcoholic steatohepatitis	Hepatobiliary disorders	2	0.00 %
Non-compaction cardiomyopathy	Congenital, familial and genetic disorders	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Non-dipping	Vascular disorders	2	0.00 %
Non-Hodgkin's lymphoma stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Nonalcoholic fatty liver disease	Hepatobiliary disorders	2	0.00 %
Noninfectious myelitis	Nervous system disorders	2	0.00 %
Noninfective conjunctivitis	Eye disorders	2	0.00 %
Nutritional condition abnormal	Investigations	2	0.00 %
Nyctalgia	General disorders and administration site conditions	2	0.00 %
Obsessive-compulsive personality disorder	Psychiatric disorders	2	0.00 %
Obsessive-compulsive symptom	Psychiatric disorders	2	0.00 %
Obstruction gastric	Gastrointestinal disorders	2	0.00 %
Obturator hernia	Gastrointestinal disorders	2	0.00 %
Ocular dysmetria	Eye disorders	2	0.00 %
Ocular sarcoidosis	Eye disorders	2	0.00 %
Oesophageal cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Oesophageal food impaction	Gastrointestinal disorders	2	0.00 %
Oesophageal obstruction	Gastrointestinal disorders	2	0.00 %
Oesophageal ulcer haemorrhage	Gastrointestinal disorders	2	0.00 %
Oesophagitis ulcerative	Gastrointestinal disorders	2	0.00 %
Oestrogen deficiency	Endocrine disorders	2	0.00 %
Oil acne	Skin and subcutaneous tissue disorders	2	0.00 %
Oncologic complication	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Oophorectomy	Surgical and medical procedures	2	0.00 %
Ophthalmoplegic migraine	Nervous system disorders	2	0.00 %
Opportunistic infection	Infections and infestations	2	0.00 %
Opsoclonus myoclonus	Eye disorders	2	0.00 %
Oral hyperaesthesia	Gastrointestinal disorders	2	0.00 %
Oral pigmentation	Gastrointestinal disorders	2	0.00 %
Oral surgery	Surgical and medical procedures	2	0.00 %
Orbital haemorrhage	Eye disorders	2	0.00 %
Orthopaedic examination abnormal	Investigations	2	0.00 %
Orthostatic tremor	Nervous system disorders	2	0.00 %
Osmophobia	Psychiatric disorders	2	0.00 %
Osteosclerosis	Musculoskeletal and connective tissue disorders	2	0.00 %
Otitis externa fungal	Infections and infestations	2	0.00 %
Ovarian abscess	Infections and infestations	2	0.00 %
Ovarian cyst torsion	Reproductive system and breast disorders	2	0.00 %
Ovarian germ cell teratoma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Ovarian necrosis	Reproductive system and breast disorders	2	0.00 %
Ovarian prolapse	Reproductive system and breast disorders	2	0.00 %
Overflow diarrhoea	Gastrointestinal disorders	2	0.00 %
Overgrowth bacterial	Infections and infestations	2	0.00 %
Overlap syndrome	Immune system disorders	2	0.00 %
Pacemaker generated arrhythmia	General disorders and administration site conditions	2	0.00 %
Palmoplantar keratoderma	Skin and subcutaneous tissue disorders	2	0.00 %
Pancreatic calcification	Gastrointestinal disorders	2	0.00 %
Pancreatic duct dilatation	Gastrointestinal disorders	2	0.00 %
Pancreatic mass	Gastrointestinal disorders	2	0.00 %
Pancreatic pseudocyst	Gastrointestinal disorders	2	0.00 %
Panophthalmitis	Eye disorders	2	0.00 %
Paragonimiasis	Infections and infestations	2	0.00 %
Paranasal sinus hyposecretion	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Paraneoplastic arthritis	Musculoskeletal and connective tissue disorders	2	0.00 %
Parapharyngeal space infection	Infections and infestations	2	0.00 %
Parasite stool test positive	Investigations	2	0.00 %
Paroxysmal sympathetic hyperactivity	Nervous system disorders	2	0.00 %
Parvovirus infection	Infections and infestations	2	0.00 %
Patent ductus arteriosus	Congenital, familial and genetic disorders	2	0.00 %
Patient dissatisfaction with treatment	Social circumstances	2	0.00 %
Patient uncooperative	Social circumstances	2	0.00 %
Pectus excavatum	Congenital, familial and genetic disorders	2	0.00 %
Pelvi-ureteric obstruction	Renal and urinary disorders	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Pelvic haematoma	Reproductive system and breast disorders	2	0.00 %
Pelvic mass	General disorders and administration site conditions	2	0.00 %
Pelvic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Penile contusion	Injury, poisoning and procedural complications	2	0.00 %
Perihepatic discomfort	Hepatobiliary disorders	2	0.00 %
Perinatal stroke	Nervous system disorders	2	0.00 %
Perineal abscess	Infections and infestations	2	0.00 %
Perineal rash	Reproductive system and breast disorders	2	0.00 %
Perineal ulceration	Reproductive system and breast disorders	2	0.00 %
Perinephric collection	Renal and urinary disorders	2	0.00 %
Periorbital infection	Infections and infestations	2	0.00 %
Periorbital irritation	Eye disorders	2	0.00 %
Peripartum cardiomyopathy	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Peripheral artery aneurysm rupture	Vascular disorders	2	0.00 %
Peripheral artery dissection	Vascular disorders	2	0.00 %
Peripheral nerve destruction	Surgical and medical procedures	2	0.00 %
Peripheral vein stenosis	Vascular disorders	2	0.00 %
Periprosthetic fracture	Injury, poisoning and procedural complications	2	0.00 %
Peristalsis visible	Gastrointestinal disorders	2	0.00 %
Peritoneal haematoma	Gastrointestinal disorders	2	0.00 %
Periventricular leukomalacia	Nervous system disorders	2	0.00 %
pH body fluid decreased	Investigations	2	0.00 %
Phalen's test positive	Investigations	2	0.00 %
Phantom shocks	General disorders and administration site conditions	2	0.00 %
Pharyngeal contusion	Injury, poisoning and procedural complications	2	0.00 %
Pharyngeal pustule	Infections and infestations	2	0.00 %
Physical capacity evaluation	Investigations	2	0.00 %
Physical examination abnormal	Investigations	2	0.00 %
Physiotherapy	Surgical and medical procedures	2	0.00 %
Pickwickian syndrome	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Picornavirus infection	Infections and infestations	2	0.00 %
Pigmentary glaucoma	Eye disorders	2	0.00 %
Pigmentation lip	Gastrointestinal disorders	2	0.00 %
Pinguecula	Eye disorders	2	0.00 %
Pituitary enlargement	Endocrine disorders	2	0.00 %
Pituitary haemorrhage	Endocrine disorders	2	0.00 %
Placental transfusion syndrome	Blood and lymphatic system disorders	2	0.00 %
Plasma cell leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Plasma viscosity abnormal	Investigations	2	0.00 %
Platelet count	Investigations	2	0.00 %
Platelet factor 4	Investigations	2	0.00 %
Platelet factor 4 increased	Investigations	2	0.00 %
Plateletcrit increased	Investigations	2	0.00 %
Pleural fluid analysis abnormal	Investigations	2	0.00 %
Pleural infection	Infections and infestations	2	0.00 %
Plica syndrome	Musculoskeletal and connective tissue disorders	2	0.00 %
Pneumatosis intestinalis	Gastrointestinal disorders	2	0.00 %
Pneumocephalus	Injury, poisoning and procedural complications	2	0.00 %
Pneumococcal sepsis	Infections and infestations	2	0.00 %
Pneumonia haemophilus	Infections and infestations	2	0.00 %
Polydactyly	Congenital, familial and genetic disorders	2	0.00 %
Polyneuropathy idiopathic progressive	Nervous system disorders	2	0.00 %
Poor personal hygiene	Social circumstances	2	0.00 %
Portal vein embolism	Hepatobiliary disorders	2	0.00 %
Portal venous gas	Gastrointestinal disorders	2	0.00 %
Post abortion haemorrhage	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Post procedural fistula	Injury, poisoning and procedural complications	2	0.00 %
Post procedural myocardial infarction	Injury, poisoning and procedural complications	2	0.00 %
Post stroke epilepsy	Nervous system disorders	2	0.00 %
Posterior cortical atrophy	Nervous system disorders	2	0.00 %
Posterior tibial tendon dysfunction	Musculoskeletal and connective tissue disorders	2	0.00 %
Postoperative thrombosis	Injury, poisoning and procedural complications	2	0.00 %
Postpartum disorder	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Postpartum state	Pregnancy, puerperium and perinatal conditions	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Postpartum venous thrombosis	Vascular disorders	2	0.00 %
Posturing	Psychiatric disorders	2	0.00 %
Pouchitis	Gastrointestinal disorders	2	0.00 %
Poverty of speech	Psychiatric disorders	2	0.00 %
Preauricular cyst	Congenital, familial and genetic disorders	2	0.00 %
Precancerous condition	General disorders and administration site conditions	2	0.00 %
Pregnancy test	Investigations	2	0.00 %
Pregnancy test false positive	Investigations	2	0.00 %
Pregnancy test positive	Investigations	2	0.00 %
Pregnancy with implant contraceptive	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Presbyastasis	Nervous system disorders	2	0.00 %
Primary mediastinal large B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Procalcitonin abnormal	Investigations	2	0.00 %
Procedural site reaction	Injury, poisoning and procedural complications	2	0.00 %
Proctitis herpes	Infections and infestations	2	0.00 %
Product closure issue	Product issues	2	0.00 %
Product contamination chemical	Product issues	2	0.00 %
Product selection error	Injury, poisoning and procedural complications	2	0.00 %
Progesterone increased	Investigations	2	0.00 %
Progressive macular hypomelanosis	Skin and subcutaneous tissue disorders	2	0.00 %
Progressive multifocal leukoencephalopathy	Infections and infestations	2	0.00 %
Progressive multiple sclerosis	Nervous system disorders	2	0.00 %
Prolactin-producing pituitary tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Promotion of wound healing	Surgical and medical procedures	2	0.00 %
Prosopagnosia	Nervous system disorders	2	0.00 %
Prostate cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Prostatic adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Prostatic cyst	Reproductive system and breast disorders	2	0.00 %
Protein deficiency	Metabolism and nutrition disorders	2	0.00 %
Proteus test positive	Investigations	2	0.00 %
Pseudodementia	Psychiatric disorders	2	0.00 %
Pseudohallucination	Psychiatric disorders	2	0.00 %
Pseudomonal bacteraemia	Infections and infestations	2	0.00 %
Pseudomonal sepsis	Infections and infestations	2	0.00 %
Pseudomonas test positive	Investigations	2	0.00 %
Pseudomyopia	Eye disorders	2	0.00 %
Pseudopoly	General disorders and administration site conditions	2	0.00 %
Pseudovasculitis	Vascular disorders	2	0.00 %
Psoriasis area severity index decreased	Investigations	2	0.00 %
Psychogenic movement disorder	Psychiatric disorders	2	0.00 %
Puerperal pyrexia	Infections and infestations	2	0.00 %
Pulmonary hilum mass	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Pulmonary hypertensive crisis	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Pulmonary hypoplasia	Congenital, familial and genetic disorders	2	0.00 %
Pulmonary necrosis	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Pulmonary renal syndrome	Renal and urinary disorders	2	0.00 %
Pulmonary valve disease	Cardiac disorders	2	0.00 %
Pulmonary valve stenosis congenital	Congenital, familial and genetic disorders	2	0.00 %
Pulse pressure abnormal	Investigations	2	0.00 %
Pupillary deformity	Eye disorders	2	0.00 %
Pyruvate kinase increased	Investigations	2	0.00 %
Radial pulse increased	Investigations	2	0.00 %
Radiation injury	Injury, poisoning and procedural complications	2	0.00 %
Radiation sickness syndrome	Injury, poisoning and procedural complications	2	0.00 %
Radiologically isolated syndrome	Nervous system disorders	2	0.00 %
Radiotherapy	Surgical and medical procedures	2	0.00 %
Rapid eye movement sleep behaviour disorder	Psychiatric disorders	2	0.00 %
Rathke's cleft cyst	Congenital, familial and genetic disorders	2	0.00 %
Reaction to food additive	Immune system disorders	2	0.00 %
Rebound eczema	Skin and subcutaneous tissue disorders	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Rebound effect	General disorders and administration site conditions	2	0.00 %
Rectal adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Rectal polyp	Gastrointestinal disorders	2	0.00 %
Rectal spasm	Gastrointestinal disorders	2	0.00 %
Red blood cell rouleaux formation present	Investigations	2	0.00 %
Renal aplasia	Congenital, familial and genetic disorders	2	0.00 %
Renal cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Renal cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Renal cortical necrosis	Renal and urinary disorders	2	0.00 %
Renal cyst haemorrhage	Renal and urinary disorders	2	0.00 %
Renal hamartoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Renal surgery	Surgical and medical procedures	2	0.00 %
Renal transplant	Surgical and medical procedures	2	0.00 %
Renal tubular disorder	Renal and urinary disorders	2	0.00 %
Renal-limited thrombotic microangiopathy	Renal and urinary disorders	2	0.00 %
Respiratory syncytial virus test positive	Investigations	2	0.00 %
Restrictive cardiomyopathy	Cardiac disorders	2	0.00 %
Retention cyst	General disorders and administration site conditions	2	0.00 %
Retinal cyst	Eye disorders	2	0.00 %
Retinal dystrophy	Eye disorders	2	0.00 %
Retinal fovea disorder	Eye disorders	2	0.00 %
Retinal operation	Surgical and medical procedures	2	0.00 %
Retinal pigmentation	Eye disorders	2	0.00 %
Retinal scar	Eye disorders	2	0.00 %
Retinogram abnormal	Investigations	2	0.00 %
Retroperitoneal fibrosis	Gastrointestinal disorders	2	0.00 %
Retroperitoneal lymphadenopathy	Blood and lymphatic system disorders	2	0.00 %
Rhesus antibodies positive	Investigations	2	0.00 %
Rheumatoid arthritis-associated interstitial lung disease	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Rheumatoid factor	Investigations	2	0.00 %
Rhinolaryngitis	Infections and infestations	2	0.00 %
Right atrial hypertrophy	Cardiac disorders	2	0.00 %
Right ventricular systolic pressure increased	Investigations	2	0.00 %
Roseolovirus test positive	Investigations	2	0.00 %
Rotavirus infection	Infections and infestations	2	0.00 %
Rubulavirus test positive	Investigations	2	0.00 %
Ruptured ectopic pregnancy	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Salpingo-oophoritis	Infections and infestations	2	0.00 %
Sarcoid-like reaction	Skin and subcutaneous tissue disorders	2	0.00 %
SARS-CoV-1 test negative	Investigations	2	0.00 %
SARS-CoV-2 sepsis	Infections and infestations	2	0.00 %
SARS-CoV-2 test false negative	Investigations	2	0.00 %
Scan abnormal	Investigations	2	0.00 %
Schizoaffective disorder	Psychiatric disorders	2	0.00 %
Scleral oedema	Eye disorders	2	0.00 %
Sclerodactylia	Musculoskeletal and connective tissue disorders	2	0.00 %
Scleroderma renal crisis	Renal and urinary disorders	2	0.00 %
Scrotal angiokeratoma	Reproductive system and breast disorders	2	0.00 %
Scrotal dermatitis	Reproductive system and breast disorders	2	0.00 %
Scrotal infection	Infections and infestations	2	0.00 %
Sebaceous gland disorder	Skin and subcutaneous tissue disorders	2	0.00 %
Sebaceous gland infection	Infections and infestations	2	0.00 %
Secondary cerebellar degeneration	Nervous system disorders	2	0.00 %
Secondary hypothyroidism	Endocrine disorders	2	0.00 %
Secondary syphilis	Infections and infestations	2	0.00 %
Secondary thrombocytosis	Blood and lymphatic system disorders	2	0.00 %
Semen analysis abnormal	Investigations	2	0.00 %
Semen volume increased	Investigations	2	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Sepsis neonatal	Infections and infestations	2	0.00 %
Serratia test positive	Investigations	2	0.00 %
Severe asthma with fungal sensitisation	Infections and infestations	2	0.00 %
Severe invasive streptococcal infection	Infections and infestations	2	0.00 %
Sexual inhibition	Psychiatric disorders	2	0.00 %
Shoulder operation	Surgical and medical procedures	2	0.00 %
Shunt thrombosis	Injury, poisoning and procedural complications	2	0.00 %
Sickle cell anaemia	Congenital, familial and genetic disorders	2	0.00 %
Sickle cell disease	Congenital, familial and genetic disorders	2	0.00 %
Skin malformation	Congenital, familial and genetic disorders	2	0.00 %
Skull malformation	Congenital, familial and genetic disorders	2	0.00 %
Skull X-ray	Investigations	2	0.00 %
Sleep disorder due to general medical condition, hypersomnia type	Psychiatric disorders	2	0.00 %
Small intestinal resection	Surgical and medical procedures	2	0.00 %
Smear cervix	Investigations	2	0.00 %
Snapping hip syndrome	Musculoskeletal and connective tissue disorders	2	0.00 %
Social (pragmatic) communication disorder	Psychiatric disorders	2	0.00 %
Soft tissue necrosis	Musculoskeletal and connective tissue disorders	2	0.00 %
Soft tissue sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Somatosensory evoked potentials abnormal	Investigations	2	0.00 %
Somniphobia	Psychiatric disorders	2	0.00 %
Sperm concentration abnormal	Investigations	2	0.00 %
Spermatocele	Reproductive system and breast disorders	2	0.00 %
Sphincter of Oddi dysfunction	Hepatobiliary disorders	2	0.00 %
Spinal cord injury thoracic	Injury, poisoning and procedural complications	2	0.00 %
Spinal flattening	Musculoskeletal and connective tissue disorders	2	0.00 %
Spinal laminectomy	Surgical and medical procedures	2	0.00 %
Spinocerebellar disorder	Nervous system disorders	2	0.00 %
Splenic artery aneurysm	Gastrointestinal disorders	2	0.00 %
Splenic artery embolisation	Surgical and medical procedures	2	0.00 %
Splenic haemorrhage	Blood and lymphatic system disorders	2	0.00 %
Splenic infection	Infections and infestations	2	0.00 %
Splenic injury	Injury, poisoning and procedural complications	2	0.00 %
Spontaneous ejaculation	Reproductive system and breast disorders	2	0.00 %
Spontaneous hyphaema	Eye disorders	2	0.00 %
Staphylococcal abscess	Infections and infestations	2	0.00 %
Staphylococcal impetigo	Infections and infestations	2	0.00 %
Stoma site pain	Injury, poisoning and procedural complications	2	0.00 %
Stoma site pruritus	Injury, poisoning and procedural complications	2	0.00 %
Streptococcal bacteraemia	Infections and infestations	2	0.00 %
Stress echocardiogram abnormal	Investigations	2	0.00 %
Stroke volume decreased	Investigations	2	0.00 %
Subacute hepatic failure	Hepatobiliary disorders	2	0.00 %
Subcorneal pustular dermatosis	Skin and subcutaneous tissue disorders	2	0.00 %
Subendocardial ischaemia	Cardiac disorders	2	0.00 %
Subretinal haematoma	Eye disorders	2	0.00 %
Substance abuse	Psychiatric disorders	2	0.00 %
Superior mesenteric artery dissection	Gastrointestinal disorders	2	0.00 %
Suspected product tampering	Product issues	2	0.00 %
Suture insertion	Surgical and medical procedures	2	0.00 %
Sweat gland disorder	Skin and subcutaneous tissue disorders	2	0.00 %
Synovial fluid crystal present	Investigations	2	0.00 %
Synovial fluid white blood cells positive	Investigations	2	0.00 %
Systemic candida	Infections and infestations	2	0.00 %
Systemic viral infection	Infections and infestations	2	0.00 %
Talipes	Congenital, familial and genetic disorders	2	0.00 %
Tandem gait test abnormal	Investigations	2	0.00 %
Tender joint count	Investigations	2	0.00 %
Tenodesis	Surgical and medical procedures	2	0.00 %
Term birth	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Testicular abscess	Infections and infestations	2	0.00 %
Testicular haemorrhage	Reproductive system and breast disorders	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Testicular injury	Injury, poisoning and procedural complications	2	0.00 %
Testicular neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Testicular retraction	Reproductive system and breast disorders	2	0.00 %
Therapeutic product effect prolonged	General disorders and administration site conditions	2	0.00 %
Therapy cessation	Surgical and medical procedures	2	0.00 %
Thoracic spinal stenosis	Musculoskeletal and connective tissue disorders	2	0.00 %
Threat of redundancy	Social circumstances	2	0.00 %
Throat cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Thrombophlebitis septic	Infections and infestations	2	0.00 %
Thyroid gland scan abnormal	Investigations	2	0.00 %
Thyroiditis chronic	Endocrine disorders	2	0.00 %
Tissue discolouration	General disorders and administration site conditions	2	0.00 %
Tongue polyp	Gastrointestinal disorders	2	0.00 %
Tonsillar cyst	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Tooth resorption	Gastrointestinal disorders	2	0.00 %
Torus fracture	Injury, poisoning and procedural complications	2	0.00 %
Total cholesterol/HDL ratio decreased	Investigations	2	0.00 %
Total complement activity decreased	Investigations	2	0.00 %
Toxic neuropathy	Nervous system disorders	2	0.00 %
Toxoplasma serology positive	Investigations	2	0.00 %
Tracheal deviation	Injury, poisoning and procedural complications	2	0.00 %
Tracheostomy	Surgical and medical procedures	2	0.00 %
Tracheostomy malfunction	Injury, poisoning and procedural complications	2	0.00 %
Transaminases decreased	Investigations	2	0.00 %
Transferrin saturation abnormal	Investigations	2	0.00 %
Transferrin saturation increased	Investigations	2	0.00 %
Transient lingual papillitis	Gastrointestinal disorders	2	0.00 %
Transient tachypnoea of the newborn	Respiratory, thoracic and mediastinal disorders	2	0.00 %
Transplant dysfunction	Injury, poisoning and procedural complications	2	0.00 %
Transplant failure	Injury, poisoning and procedural complications	2	0.00 %
Transurethral prostatectomy	Surgical and medical procedures	2	0.00 %
Traumatic heart injury	Injury, poisoning and procedural complications	2	0.00 %
Traumatic liver injury	Injury, poisoning and procedural complications	2	0.00 %
Trendelenburg's symptom	Musculoskeletal and connective tissue disorders	2	0.00 %
Trichotillomania	Psychiatric disorders	2	0.00 %
Trisomy 13	Congenital, familial and genetic disorders	2	0.00 %
Troponin normal	Investigations	2	0.00 %
Trousseau's sign	Metabolism and nutrition disorders	2	0.00 %
Tubulointerstitial nephritis and uveitis syndrome	Renal and urinary disorders	2	0.00 %
Tularaemia	Infections and infestations	2	0.00 %
Tumour inflammation	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Tumour lysis syndrome	Metabolism and nutrition disorders	2	0.00 %
Tumour marker abnormal	Investigations	2	0.00 %
Tumour thrombosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Tympanometry abnormal	Investigations	2	0.00 %
Type IIa hyperlipidaemia	Congenital, familial and genetic disorders	2	0.00 %
Typhoid fever	Infections and infestations	2	0.00 %
Ultrasound foetal abnormal	Investigations	2	0.00 %
Umbilical erythema	Skin and subcutaneous tissue disorders	2	0.00 %
Undifferentiated spondyloarthritis	Musculoskeletal and connective tissue disorders	2	0.00 %
Urea urine abnormal	Investigations	2	0.00 %
Ureaplasma infection	Infections and infestations	2	0.00 %
Ureteric obstruction	Renal and urinary disorders	2	0.00 %
Urethral intrinsic sphincter deficiency	Renal and urinary disorders	2	0.00 %
Urethral spasm	Renal and urinary disorders	2	0.00 %
Urethral stenosis	Renal and urinary disorders	2	0.00 %
Urethral syndrome	Renal and urinary disorders	2	0.00 %
Urinary bladder rupture	Renal and urinary disorders	2	0.00 %
Urinary tract infection staphylococcal	Infections and infestations	2	0.00 %
Urinary tract neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Urine potassium decreased	Investigations	2	0.00 %
Urine sodium increased	Investigations	2	0.00 %
Urinoma	Renal and urinary disorders	2	0.00 %
Urogenital disorder	Renal and urinary disorders	2	0.00 %
Urticaria pigmentosa	Skin and subcutaneous tissue disorders	2	0.00 %
Uterine hypotonus	Pregnancy, puerperium and perinatal conditions	2	0.00 %
Uterine malposition	Reproductive system and breast disorders	2	0.00 %
Vaccination site fibrosis	General disorders and administration site conditions	2	0.00 %
Vaccination site joint infection	Infections and infestations	2	0.00 %
Vaccination site vasculitis	General disorders and administration site conditions	2	0.00 %
Vaccinia virus infection	Infections and infestations	2	0.00 %
Vaginal erosion	Reproductive system and breast disorders	2	0.00 %
Vaginal haematoma	Reproductive system and breast disorders	2	0.00 %
Vaginal oedema	Reproductive system and breast disorders	2	0.00 %
Varicella post vaccine	Infections and infestations	2	0.00 %
Varicella zoster pneumonia	Infections and infestations	2	0.00 %
Vascular access malfunction	Injury, poisoning and procedural complications	2	0.00 %
Vascular test abnormal	Investigations	2	0.00 %
Vein wall hypertrophy	Vascular disorders	2	0.00 %
Vena cava embolism	Vascular disorders	2	0.00 %
Venoocclusive liver disease	Hepatobiliary disorders	2	0.00 %
Venous hypertension	Vascular disorders	2	0.00 %
Venous operation	Surgical and medical procedures	2	0.00 %
Venous oxygen partial pressure decreased	Investigations	2	0.00 %
Venous perforation	Vascular disorders	2	0.00 %
Venous thrombosis in pregnancy	Vascular disorders	2	0.00 %
Ventricular hypoplasia	Congenital, familial and genetic disorders	2	0.00 %
Ventricular pre-excitation	Cardiac disorders	2	0.00 %
Vertebral wedging	Musculoskeletal and connective tissue disorders	2	0.00 %
Vessel puncture site erythema	General disorders and administration site conditions	2	0.00 %
Vessel puncture site swelling	General disorders and administration site conditions	2	0.00 %
Viraemia	Infections and infestations	2	0.00 %
Viral load	Investigations	2	0.00 %
Viral myositis	Infections and infestations	2	0.00 %
Viral sinusitis	Infections and infestations	2	0.00 %
Viral test	Investigations	2	0.00 %
Visual field tests abnormal	Investigations	2	0.00 %
Vitamin B6 decreased	Investigations	2	0.00 %
Vitamin D increased	Investigations	2	0.00 %
Vth nerve injury	Injury, poisoning and procedural complications	2	0.00 %
Vulva cyst	Reproductive system and breast disorders	2	0.00 %
Vulval cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	0.00 %
Vulvovaginal disorder	Reproductive system and breast disorders	2	0.00 %
Walking distance test abnormal	Investigations	2	0.00 %
Weaning failure	Injury, poisoning and procedural complications	2	0.00 %
Weight loss diet	Surgical and medical procedures	2	0.00 %
White blood cell morphology abnormal	Investigations	2	0.00 %
Wisdom teeth removal	Surgical and medical procedures	2	0.00 %
Wound dehiscence	Injury, poisoning and procedural complications	2	0.00 %
Wound haematoma	Injury, poisoning and procedural complications	2	0.00 %
Wound sepsis	Infections and infestations	2	0.00 %
Wrist surgery	Surgical and medical procedures	2	0.00 %
Xanthelasma	Skin and subcutaneous tissue disorders	2	0.00 %
Zinc deficiency	Metabolism and nutrition disorders	2	0.00 %
Zoonotic bacterial infection	Infections and infestations	2	0.00 %
5-hydroxyindolacetic acid in urine	Investigations	1	0.00 %
5q minus syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Abdominal fat apron	Gastrointestinal disorders	1	0.00 %
Abdominal rebound tenderness	Gastrointestinal disorders	1	0.00 %
Abdominal wall cyst	Gastrointestinal disorders	1	0.00 %
Abdominal wall disorder	Gastrointestinal disorders	1	0.00 %
Abdominal wall wound	Injury, poisoning and procedural complications	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Abdominoplasty	Surgical and medical procedures	1	0.00 %
Abnormal organ growth	General disorders and administration site conditions	1	0.00 %
Abnormal palmar/plantar creases	Congenital, familial and genetic disorders	1	0.00 %
Abnormal precordial movement	Cardiac disorders	1	0.00 %
Abortion complicated	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Abortion induced incomplete	Injury, poisoning and procedural complications	1	0.00 %
Abortion infected	Infections and infestations	1	0.00 %
Abortion spontaneous complicated	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Abscess fungal	Infections and infestations	1	0.00 %
Abscess of external auditory meatus	Infections and infestations	1	0.00 %
Abscess soft tissue	Infections and infestations	1	0.00 %
Abscess sterile	General disorders and administration site conditions	1	0.00 %
Abscess sweat gland	Infections and infestations	1	0.00 %
Absence of immediate treatment response	General disorders and administration site conditions	1	0.00 %
Acantholysis	Skin and subcutaneous tissue disorders	1	0.00 %
Acanthosis nigricans	Skin and subcutaneous tissue disorders	1	0.00 %
Accelerated idioventricular rhythm	Cardiac disorders	1	0.00 %
Accessory cardiac pathway	Cardiac disorders	1	0.00 %
Accessory nerve disorder	Nervous system disorders	1	0.00 %
Achromobacter infection	Infections and infestations	1	0.00 %
Acid base balance	Investigations	1	0.00 %
Acid peptic disease	Gastrointestinal disorders	1	0.00 %
Acidosis hyperchloraemic	Metabolism and nutrition disorders	1	0.00 %
Acinetobacter bacteraemia	Infections and infestations	1	0.00 %
Acinetobacter infection	Infections and infestations	1	0.00 %
Acinic cell carcinoma of salivary gland	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Acoustic stimulation tests	Investigations	1	0.00 %
Acoustic stimulation tests normal	Investigations	1	0.00 %
Acquired amegakaryocytic thrombocytopenia	Blood and lymphatic system disorders	1	0.00 %
Acquired cardiac septal defect	Cardiac disorders	1	0.00 %
Acquired factor V deficiency	Blood and lymphatic system disorders	1	0.00 %
Acquired gene mutation	Congenital, familial and genetic disorders	1	0.00 %
Acquired hydrocele	Reproductive system and breast disorders	1	0.00 %
Acquired left ventricle outflow tract obstruction	Cardiac disorders	1	0.00 %
Acquired oesophageal web	Gastrointestinal disorders	1	0.00 %
Acquired perforating dermatosis	Skin and subcutaneous tissue disorders	1	0.00 %
Acrodermatitis chronica atrophicans	Infections and infestations	1	0.00 %
Acrodermatitis enteropathica	Congenital, familial and genetic disorders	1	0.00 %
Acrodynia	Nervous system disorders	1	0.00 %
Actinomycosis	Infections and infestations	1	0.00 %
Activated protein C resistance	Blood and lymphatic system disorders	1	0.00 %
Acute hepatitis B	Infections and infestations	1	0.00 %
Acute HIV infection	Infections and infestations	1	0.00 %
Acute megakaryocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Acute monocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Acute myelomonocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Acute promyelocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Adenocarcinoma gastric	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Adenolymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Adenovirus reactivation	Infections and infestations	1	0.00 %
Adjustment disorder with mixed anxiety and depressed mood	Psychiatric disorders	1	0.00 %
Administration related reaction	Injury, poisoning and procedural complications	1	0.00 %
Administration site abscess	Infections and infestations	1	0.00 %
Administration site fibrosis	General disorders and administration site conditions	1	0.00 %
Administration site joint discomfort	General disorders and administration site conditions	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Administration site nerve damage	General disorders and administration site conditions	1	0.00 %
Administration site plaque	General disorders and administration site conditions	1	0.00 %
Administration site urticaria	General disorders and administration site conditions	1	0.00 %
Adrenal atrophy	Endocrine disorders	1	0.00 %
Adrenal gland injury	Injury, poisoning and procedural complications	1	0.00 %
Adrenal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Adrenal thrombosis	Endocrine disorders	1	0.00 %
Adrenalitis	Infections and infestations	1	0.00 %
Adrenocorticotrophic hormone deficiency	Endocrine disorders	1	0.00 %
Adrenogenital syndrome	Congenital, familial and genetic disorders	1	0.00 %
Adrenoleukodystrophy	Congenital, familial and genetic disorders	1	0.00 %
Advanced sleep phase	Nervous system disorders	1	0.00 %
Aerophobia	Psychiatric disorders	1	0.00 %
Affective ambivalence	Psychiatric disorders	1	0.00 %
Afterbirth pain	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Airway secretion clearance therapy	Surgical and medical procedures	1	0.00 %
Albumin globulin ratio abnormal	Investigations	1	0.00 %
Albumin urine	Investigations	1	0.00 %
Albumin urine absent	Investigations	1	0.00 %
Alcohol induced persisting dementia	Nervous system disorders	1	0.00 %
Alcohol test false positive	Investigations	1	0.00 %
Alcohol use disorder	Psychiatric disorders	1	0.00 %
Alcohol withdrawal syndrome	Psychiatric disorders	1	0.00 %
Alcoholic liver disease	Hepatobiliary disorders	1	0.00 %
Alcoholic pancreatitis	Gastrointestinal disorders	1	0.00 %
Alcoholic psychosis	Psychiatric disorders	1	0.00 %
Alcoholic seizure	Nervous system disorders	1	0.00 %
Aldosterone urine increased	Investigations	1	0.00 %
Alexithymia	Psychiatric disorders	1	0.00 %
Allergic bronchopulmonary mycosis	Infections and infestations	1	0.00 %
Allergic stomatitis	Gastrointestinal disorders	1	0.00 %
Allergy alert test	Investigations	1	0.00 %
Allergy prophylaxis	Surgical and medical procedures	1	0.00 %
Allergy test	Investigations	1	0.00 %
Allergy to fermented products	Immune system disorders	1	0.00 %
Allergy to synthetic fabric	Immune system disorders	1	0.00 %
Alopecia scarring	Skin and subcutaneous tissue disorders	1	0.00 %
Alpha 1 foetoprotein abnormal	Investigations	1	0.00 %
Alpha 1 foetoprotein decreased	Investigations	1	0.00 %
Alpha-2 macroglobulin increased	Investigations	1	0.00 %
Alveolar proteinosis	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Amino acid level decreased	Investigations	1	0.00 %
Ammonia abnormal	Investigations	1	0.00 %
Amniotic membrane rupture test positive	Investigations	1	0.00 %
Amphetamines	Investigations	1	0.00 %
Amyloid related imaging abnormalities	Nervous system disorders	1	0.00 %
Anaemia of chronic disease	Blood and lymphatic system disorders	1	0.00 %
Anaemia of pregnancy	Blood and lymphatic system disorders	1	0.00 %
Anal atresia	Congenital, familial and genetic disorders	1	0.00 %
Anal blister	Gastrointestinal disorders	1	0.00 %
Anal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Anal erosion	Gastrointestinal disorders	1	0.00 %
Anal fungal infection	Infections and infestations	1	0.00 %
Anal infection	Infections and infestations	1	0.00 %
Anal injury	Injury, poisoning and procedural complications	1	0.00 %
Anal sex	Social circumstances	1	0.00 %
Anal skin tags	Gastrointestinal disorders	1	0.00 %
Anal sphincter hypertonia	Gastrointestinal disorders	1	0.00 %
Analgesic drug level above therapeutic	Investigations	1	0.00 %
Analgesic drug level increased	Investigations	1	0.00 %
Anaphylactoid syndrome of pregnancy	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Anaphylaxis prophylaxis	Surgical and medical procedures	1	0.00 %
Anaplastic thyroid cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Anastomotic complication	Injury, poisoning and procedural complications	1	0.00 %
Anastomotic leak	Injury, poisoning and procedural complications	1	0.00 %
Anastomotic ulcer	Injury, poisoning and procedural complications	1	0.00 %
Anastomotic ulcer perforation	Gastrointestinal disorders	1	0.00 %
Aneurysm arteriovenous	Vascular disorders	1	0.00 %
Angiodermatitis	Skin and subcutaneous tissue disorders	1	0.00 %
Angiodysplasia	Vascular disorders	1	0.00 %
Angiofibroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Angiogram cerebral abnormal	Investigations	1	0.00 %
Angioimmunoblastic T-cell lymphoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Angiokeratoma	Skin and subcutaneous tissue disorders	1	0.00 %
Angiolipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Angiolymphoid hyperplasia with eosinophilia	Skin and subcutaneous tissue disorders	1	0.00 %
Angiotensin II abnormal	Investigations	1	0.00 %
Angiotensin II receptor type 1 antibody positive	Investigations	1	0.00 %
Anion gap abnormal	Investigations	1	0.00 %
Anisometropia	Eye disorders	1	0.00 %
Ankle deformity	Musculoskeletal and connective tissue disorders	1	0.00 %
Anodontia	Congenital, familial and genetic disorders	1	0.00 %
Anophthalmos	Congenital, familial and genetic disorders	1	0.00 %
Anorectal infection	Infections and infestations	1	0.00 %
Anotia	Congenital, familial and genetic disorders	1	0.00 %
Anterior chamber cell	Eye disorders	1	0.00 %
Anterior chamber flare	Eye disorders	1	0.00 %
Anterior chamber inflammation	Eye disorders	1	0.00 %
Anterior chamber opacity	Eye disorders	1	0.00 %
Anti B antibody positive	Investigations	1	0.00 %
Anti factor IX antibody increased	Investigations	1	0.00 %
Anti factor V antibody positive	Investigations	1	0.00 %
Anti factor VIII antibody increased	Investigations	1	0.00 %
Anti Kell antibody test positive	Investigations	1	0.00 %
Anti-glomerular basement membrane antibody positive	Investigations	1	0.00 %
Anti-insulin antibody increased	Investigations	1	0.00 %
Anti-insulin antibody positive	Investigations	1	0.00 %
Anti-melanoma differentiation-associated protein 5 antibody positive	Investigations	1	0.00 %
Anti-neuronal antibody positive	Investigations	1	0.00 %
Anti-platelet antibody	Investigations	1	0.00 %
Anti-polyethylene glycol antibody present	Investigations	1	0.00 %
Anti-prothrombin antibody positive	Investigations	1	0.00 %
Anti-saccharomyces cerevisiae antibody test positive	Investigations	1	0.00 %
Anti-SRP antibody positive	Investigations	1	0.00 %
Anti-thyroid antibody decreased	Investigations	1	0.00 %
Antibiotic therapy	Surgical and medical procedures	1	0.00 %
Antibody test	Investigations	1	0.00 %
Antibody test normal	Investigations	1	0.00 %
Anticoagulation drug level	Investigations	1	0.00 %
Anticoagulation drug level increased	Investigations	1	0.00 %
Antidepressant drug level decreased	Investigations	1	0.00 %
Antidepressant drug level increased	Investigations	1	0.00 %
Antidepressant therapy	Surgical and medical procedures	1	0.00 %
Antiinflammatory therapy	Surgical and medical procedures	1	0.00 %
Antimicrobial susceptibility test resistant	Investigations	1	0.00 %
Antineutrophil cytoplasmic antibody	Investigations	1	0.00 %
Antineutrophil cytoplasmic antibody decreased	Investigations	1	0.00 %
Antinuclear antibody negative	Investigations	1	0.00 %
Antipsychotic drug level below therapeutic	Investigations	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Antisocial personality disorder	Psychiatric disorders	1	0.00 %
Antithrombin III increased	Investigations	1	0.00 %
Antiviral prophylaxis	Surgical and medical procedures	1	0.00 %
Antiviral treatment	Surgical and medical procedures	1	0.00 %
Aorta hypoplasia	Congenital, familial and genetic disorders	1	0.00 %
Aortic aneurysm repair	Surgical and medical procedures	1	0.00 %
Aortic valve thickening	Cardiac disorders	1	0.00 %
Apgar score abnormal	Investigations	1	0.00 %
Aplasia cutis congenita	Congenital, familial and genetic disorders	1	0.00 %
Apnoea test abnormal	Investigations	1	0.00 %
Apolipoprotein B increased	Investigations	1	0.00 %
Apparent death	General disorders and administration site conditions	1	0.00 %
Appendix cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Application site abscess	Infections and infestations	1	0.00 %
Application site dermatitis	General disorders and administration site conditions	1	0.00 %
Application site discolouration	General disorders and administration site conditions	1	0.00 %
Application site hyperaesthesia	General disorders and administration site conditions	1	0.00 %
Application site joint erythema	General disorders and administration site conditions	1	0.00 %
Application site joint inflammation	General disorders and administration site conditions	1	0.00 %
Application site nerve damage	General disorders and administration site conditions	1	0.00 %
Application site odour	General disorders and administration site conditions	1	0.00 %
Application site perspiration	General disorders and administration site conditions	1	0.00 %
Application site plaque	General disorders and administration site conditions	1	0.00 %
Application site scab	General disorders and administration site conditions	1	0.00 %
Application site scar	General disorders and administration site conditions	1	0.00 %
Aquagenic pruritus	Skin and subcutaneous tissue disorders	1	0.00 %
Arachnodactyl	Congenital, familial and genetic disorders	1	0.00 %
Arboviral infection	Infections and infestations	1	0.00 %
Argyria	Skin and subcutaneous tissue disorders	1	0.00 %
Arm amputation	Surgical and medical procedures	1	0.00 %
Arterial stent insertion	Surgical and medical procedures	1	0.00 %
Arterial stiffness	Vascular disorders	1	0.00 %
Arterial wall hypertrophy	Vascular disorders	1	0.00 %
Arteriogram abnormal	Investigations	1	0.00 %
Arteriogram coronary normal	Investigations	1	0.00 %
Arteriosclerotic gangrene	Infections and infestations	1	0.00 %
Arteriovenous fistula operation	Surgical and medical procedures	1	0.00 %
Arteriovenous fistula site complication	Injury, poisoning and procedural complications	1	0.00 %
Arteriovenous fistula site haemorrhage	Injury, poisoning and procedural complications	1	0.00 %
Arteriovenous graft thrombosis	Injury, poisoning and procedural complications	1	0.00 %
Arthritis enteropathic	Musculoskeletal and connective tissue disorders	1	0.00 %
Arthritis gonococcal	Infections and infestations	1	0.00 %
Arthropod infestation	Infections and infestations	1	0.00 %
Articular disc disorder	Musculoskeletal and connective tissue disorders	1	0.00 %
Artificial insemination	Surgical and medical procedures	1	0.00 %
ASAHI related disorder	Congenital, familial and genetic disorders	1	0.00 %
Aseptic pustule	Skin and subcutaneous tissue disorders	1	0.00 %
Asherman's syndrome	Reproductive system and breast disorders	1	0.00 %
Aspartate aminotransferase	Investigations	1	0.00 %
Aspiration bone marrow	Investigations	1	0.00 %
Aspirin-exacerbated respiratory disease	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Asplenia	Congenital, familial and genetic disorders	1	0.00 %
Asteatosis	Skin and subcutaneous tissue disorders	1	0.00 %
Astrocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Asymmetric crying facies	Congenital, familial and genetic disorders	1	0.00 %
Asymmetric di-methylarginine increased	Investigations	1	0.00 %
Asymmetric thigh fold	Musculoskeletal and connective tissue disorders	1	0.00 %
Athetosis	Nervous system disorders	1	0.00 %
Athletic heart syndrome	Cardiac disorders	1	0.00 %
Atopic keratoconjunctivitis	Eye disorders	1	0.00 %
Atrial hypertrophy	Cardiac disorders	1	0.00 %
Atrophic thyroiditis	Immune system disorders	1	0.00 %
Attention-seeking behaviour	Psychiatric disorders	1	0.00 %
Aural polyp	Ear and labyrinth disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Auricular haematoma	Injury, poisoning and procedural complications	1	0.00 %
Auscultation	Investigations	1	0.00 %
Autoantibody negative	Investigations	1	0.00 %
Autoantibody test	Investigations	1	0.00 %
Autoimmune cholangitis	Hepatobiliary disorders	1	0.00 %
Autoimmune enteropathy	Gastrointestinal disorders	1	0.00 %
Autoimmune nephritis	Renal and urinary disorders	1	0.00 %
Autoimmune pancytopenia	Blood and lymphatic system disorders	1	0.00 %
Automatism epileptic	Psychiatric disorders	1	0.00 %
B-cell small lymphocytic lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Bacillus infection	Infections and infestations	1	0.00 %
Bacterial parotitis	Infections and infestations	1	0.00 %
Bacterial rhinitis	Infections and infestations	1	0.00 %
Bacterial test negative	Investigations	1	0.00 %
Bacterial translocation	Infections and infestations	1	0.00 %
Balance test	Investigations	1	0.00 %
Band neutrophil count decreased	Investigations	1	0.00 %
Bandaemia	Blood and lymphatic system disorders	1	0.00 %
Bartonella test positive	Investigations	1	0.00 %
Base excess abnormal	Investigations	1	0.00 %
Basilar artery aneurysm	Nervous system disorders	1	0.00 %
Basophil percentage decreased	Investigations	1	0.00 %
Bed sharing	Social circumstances	1	0.00 %
Behaviour disorder due to a general medical condition	Psychiatric disorders	1	0.00 %
Behavioural induced insufficient sleep syndrome	Nervous system disorders	1	0.00 %
Bence Jones proteinuria	Renal and urinary disorders	1	0.00 %
Bendopnoea	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Benign bone neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Benign enlargement of the subarachnoid spaces	Nervous system disorders	1	0.00 %
Benign familial haematuria	Congenital, familial and genetic disorders	1	0.00 %
Benign lung neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Benign neoplasm of cervix uteri	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Benign neoplasm of testis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Benign ovarian tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Beta 2 microglobulin abnormal	Investigations	1	0.00 %
Beta 2 microglobulin urine increased	Investigations	1	0.00 %
Beta globulin	Investigations	1	0.00 %
Beta globulin abnormal	Investigations	1	0.00 %
Bezoar	Gastrointestinal disorders	1	0.00 %
Bezold-Jarisch reflex	Cardiac disorders	1	0.00 %
Bile output	Investigations	1	0.00 %
Bile output abnormal	Investigations	1	0.00 %
Biliary fistula	Hepatobiliary disorders	1	0.00 %
Biliary hamartoma	Congenital, familial and genetic disorders	1	0.00 %
Biliary obstruction	Hepatobiliary disorders	1	0.00 %
Binge drinking	Psychiatric disorders	1	0.00 %
Biopsy	Investigations	1	0.00 %
Biopsy bone	Investigations	1	0.00 %
Biopsy endometrium	Investigations	1	0.00 %
Biopsy heart abnormal	Investigations	1	0.00 %
Biopsy intestine abnormal	Investigations	1	0.00 %
Biopsy kidney abnormal	Investigations	1	0.00 %
Biopsy lymph gland normal	Investigations	1	0.00 %
Biopsy muscle abnormal	Investigations	1	0.00 %
Biopsy peripheral nerve	Investigations	1	0.00 %
Biopsy skin abnormal	Investigations	1	0.00 %
Bipolar II disorder	Psychiatric disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Birth trauma	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Bladder adenocarcinoma stage unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Bladder catheter permanent	Surgical and medical procedures	1	0.00 %
Bladder cyst	Renal and urinary disorders	1	0.00 %
Bladder diverticulum	Renal and urinary disorders	1	0.00 %
Bladder fibrosis	Renal and urinary disorders	1	0.00 %
Bladder necrosis	Renal and urinary disorders	1	0.00 %
Bladder ulcer	Renal and urinary disorders	1	0.00 %
Blast cell crisis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Blast cell proliferation	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Blast cells	Investigations	1	0.00 %
Blast cells present	Investigations	1	0.00 %
Blastic plasmacytoid dendritic cell neoplasia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Bleeding time	Investigations	1	0.00 %
Blepharal pigmentation	Eye disorders	1	0.00 %
Blepharophimosis	Eye disorders	1	0.00 %
Blood 1,25-dihydroxycholecalciferol increased	Investigations	1	0.00 %
Blood acid phosphatase increased	Investigations	1	0.00 %
Blood albumin	Investigations	1	0.00 %
Blood alcohol abnormal	Investigations	1	0.00 %
Blood aluminium increased	Investigations	1	0.00 %
Blood androstenedione increased	Investigations	1	0.00 %
Blood antidiuretic hormone increased	Investigations	1	0.00 %
Blood beta-D-glucan positive	Investigations	1	0.00 %
Blood caffeine decreased	Investigations	1	0.00 %
Blood chromium decreased	Investigations	1	0.00 %
Blood chromogranin A increased	Investigations	1	0.00 %
Blood copper	Investigations	1	0.00 %
Blood corticotrophin	Investigations	1	0.00 %
Blood corticotrophin decreased	Investigations	1	0.00 %
Blood creatine abnormal	Investigations	1	0.00 %
Blood creatine phosphokinase MB	Investigations	1	0.00 %
Blood creatine phosphokinase MB abnormal	Investigations	1	0.00 %
Blood creatine phosphokinase MB decreased	Investigations	1	0.00 %
Blood creatine phosphokinase normal	Investigations	1	0.00 %
Blood electrolytes increased	Investigations	1	0.00 %
Blood erythropoietin decreased	Investigations	1	0.00 %
Blood gases normal	Investigations	1	0.00 %
Blood glucagon decreased	Investigations	1	0.00 %
Blood gonadotrophin increased	Investigations	1	0.00 %
Blood growth hormone	Investigations	1	0.00 %
Blood growth hormone decreased	Investigations	1	0.00 %
Blood HIV RNA increased	Investigations	1	0.00 %
Blood homocysteine decreased	Investigations	1	0.00 %
Blood immunoglobulin A	Investigations	1	0.00 %
Blood immunoglobulin A abnormal	Investigations	1	0.00 %
Blood immunoglobulin E decreased	Investigations	1	0.00 %
Blood immunoglobulin G	Investigations	1	0.00 %
Blood immunoglobulin M abnormal	Investigations	1	0.00 %
Blood lead	Investigations	1	0.00 %
Blood magnesium abnormal	Investigations	1	0.00 %
Blood parathyroid hormone abnormal	Investigations	1	0.00 %
Blood phosphorus	Investigations	1	0.00 %
Blood phosphorus abnormal	Investigations	1	0.00 %
Blood pressure orthostatic	Investigations	1	0.00 %
Blood pressure orthostatic increased	Investigations	1	0.00 %
Blood pressure systolic inspiratory decreased	Investigations	1	0.00 %
Blood product transfusion dependent	Social circumstances	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Blood pyruvic acid increased	Investigations	1	0.00 %
Blood testosterone abnormal	Investigations	1	0.00 %
Blood testosterone free decreased	Investigations	1	0.00 %
Blood thromboplastin increased	Investigations	1	0.00 %
Blood thyroid stimulating hormone normal	Investigations	1	0.00 %
Blood urea	Investigations	1	0.00 %
Blood urea nitrogen/creatinine ratio decreased	Investigations	1	0.00 %
Blood uric acid	Investigations	1	0.00 %
Blood viscosity decreased	Investigations	1	0.00 %
Blood zinc abnormal	Investigations	1	0.00 %
Blunted affect	Psychiatric disorders	1	0.00 %
Body height abnormal	Investigations	1	0.00 %
Bone atrophy	Musculoskeletal and connective tissue disorders	1	0.00 %
Bone demineralisation	Musculoskeletal and connective tissue disorders	1	0.00 %
Bone density abnormal	Investigations	1	0.00 %
Bone density increased	Investigations	1	0.00 %
Bone development abnormal	Musculoskeletal and connective tissue disorders	1	0.00 %
Bone erosion	Musculoskeletal and connective tissue disorders	1	0.00 %
Bone formation increased	Musculoskeletal and connective tissue disorders	1	0.00 %
Bone fragmentation	Injury, poisoning and procedural complications	1	0.00 %
Bone hypertrophy	Musculoskeletal and connective tissue disorders	1	0.00 %
Bone marrow infiltration	Blood and lymphatic system disorders	1	0.00 %
Bone marrow oedema syndrome	Blood and lymphatic system disorders	1	0.00 %
Bone marrow transplant	Surgical and medical procedures	1	0.00 %
Bone tuberculosis	Infections and infestations	1	0.00 %
Borderline ovarian tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Botulinum toxin injection	Surgical and medical procedures	1	0.00 %
Brachial artery entrapment syndrome	Vascular disorders	1	0.00 %
Brachial pulse increased	Investigations	1	0.00 %
Brachiocephalic artery occlusion	Vascular disorders	1	0.00 %
Brachiocephalic artery stenosis	Vascular disorders	1	0.00 %
Brachiocephalic vein occlusion	Vascular disorders	1	0.00 %
Brachyolmia	Congenital, familial and genetic disorders	1	0.00 %
BRAF gene mutation	Congenital, familial and genetic disorders	1	0.00 %
Brain empyema	Infections and infestations	1	0.00 %
Brain natriuretic peptide	Investigations	1	0.00 %
Brain natriuretic peptide decreased	Investigations	1	0.00 %
Brain neoplasm benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Brain stem haematoma	Nervous system disorders	1	0.00 %
Branchial cyst	Congenital, familial and genetic disorders	1	0.00 %
Breast cancer in situ	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Breast cancer stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Breast conserving surgery	Surgical and medical procedures	1	0.00 %
Breast cyst drainage	Surgical and medical procedures	1	0.00 %
Breast disorder male	Reproductive system and breast disorders	1	0.00 %
Breast implant palpable	General disorders and administration site conditions	1	0.00 %
Breast malformation	Congenital, familial and genetic disorders	1	0.00 %
Breast milk substitute intolerance	Metabolism and nutrition disorders	1	0.00 %
Breast prosthesis removal	Surgical and medical procedures	1	0.00 %
Breast scan	Investigations	1	0.00 %
Breast scan abnormal	Investigations	1	0.00 %
Breast ulceration	Reproductive system and breast disorders	1	0.00 %
Breech delivery	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Brief psychotic disorder without marked stressors	Psychiatric disorders	1	0.00 %
Brief psychotic disorder, with postpartum onset	Psychiatric disorders	1	0.00 %
Bronchial dysplasia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Bronchial injury	Injury, poisoning and procedural complications	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Bronchial neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Bronchopulmonary dysplasia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Brucella test positive	Investigations	1	0.00 %
Brucellosis	Infections and infestations	1	0.00 %
Brudzinski's sign	Nervous system disorders	1	0.00 %
Brunner's gland hyperplasia	Gastrointestinal disorders	1	0.00 %
Bulimia nervosa	Psychiatric disorders	1	0.00 %
Bullous oedema of the bladder	Renal and urinary disorders	1	0.00 %
Burn dressing	Surgical and medical procedures	1	0.00 %
Burns first degree	Injury, poisoning and procedural complications	1	0.00 %
CADASIL	Congenital, familial and genetic disorders	1	0.00 %
Cafe au lait spots	Skin and subcutaneous tissue disorders	1	0.00 %
Caffeine allergy	Immune system disorders	1	0.00 %
Calcification metastatic	Metabolism and nutrition disorders	1	0.00 %
Calcification of muscle	Musculoskeletal and connective tissue disorders	1	0.00 %
Callus formation delayed	Musculoskeletal and connective tissue disorders	1	0.00 %
Campylobacter colitis	Infections and infestations	1	0.00 %
Cancer fatigue	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cancer gene carrier	Congenital, familial and genetic disorders	1	0.00 %
Capillary nail refill test	Investigations	1	0.00 %
Capillary permeability	Investigations	1	0.00 %
Capnocytophaga sepsis	Infections and infestations	1	0.00 %
Capsular warning syndrome	Nervous system disorders	1	0.00 %
Carbon dioxide abnormal	Investigations	1	0.00 %
Carbon monoxide poisoning	Injury, poisoning and procedural complications	1	0.00 %
Carboxyhaemoglobin decreased	Investigations	1	0.00 %
Carcinoid crisis	Endocrine disorders	1	0.00 %
Carcinoid tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Carcinoid tumour of the gastrointestinal tract	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Carcinoid tumour pulmonary	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Carcinoma in situ	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cardiac arrest neonatal	Cardiac disorders	1	0.00 %
Cardiac clearance	Investigations	1	0.00 %
Cardiac contusion	Injury, poisoning and procedural complications	1	0.00 %
Cardiac herniation	Injury, poisoning and procedural complications	1	0.00 %
Cardiac index increased	Investigations	1	0.00 %
Cardiac output	Investigations	1	0.00 %
Cardiac perfusion defect	Cardiac disorders	1	0.00 %
Cardiac resynchronisation therapy	Surgical and medical procedures	1	0.00 %
Cardiac stress test normal	Investigations	1	0.00 %
Cardiac valve discolouration	Cardiac disorders	1	0.00 %
Cardiac valve rupture	Injury, poisoning and procedural complications	1	0.00 %
Cardiac vein dissection	Injury, poisoning and procedural complications	1	0.00 %
Cardiac vein perforation	Injury, poisoning and procedural complications	1	0.00 %
Cardio-ankle vascular index	Investigations	1	0.00 %
Cardiomyopathy alcoholic	Cardiac disorders	1	0.00 %
Cardiovascular function test abnormal	Investigations	1	0.00 %
Carnitine palmitoyltransferase deficiency	Congenital, familial and genetic disorders	1	0.00 %
Carotid artery perforation	Nervous system disorders	1	0.00 %
Carotid artery stent insertion	Surgical and medical procedures	1	0.00 %
Carotid pulse decreased	Investigations	1	0.00 %
Carotid pulse increased	Investigations	1	0.00 %
Carpal collapse	Musculoskeletal and connective tissue disorders	1	0.00 %
Carpal tunnel decompression	Surgical and medical procedures	1	0.00 %
Cartilage hypertrophy	Musculoskeletal and connective tissue disorders	1	0.00 %
Cartilage neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cataract cortical	Eye disorders	1	0.00 %
Cataract operation	Surgical and medical procedures	1	0.00 %
Catecholamines urine increased	Investigations	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Catheter placement	Surgical and medical procedures	1	0.00 %
Catheter site haematoma	General disorders and administration site conditions	1	0.00 %
Catheter site swelling	General disorders and administration site conditions	1	0.00 %
Catheterisation cardiac abnormal	Investigations	1	0.00 %
Caudal regression syndrome	Congenital, familial and genetic disorders	1	0.00 %
Cautery to nose	Surgical and medical procedures	1	0.00 %
Cavernous sinus syndrome	Nervous system disorders	1	0.00 %
CD4/CD8 ratio decreased	Investigations	1	0.00 %
CD8 lymphocyte percentage decreased	Investigations	1	0.00 %
CD8 lymphocytes increased	Investigations	1	0.00 %
Cell marker decreased	Investigations	1	0.00 %
Cell marker increased	Investigations	1	0.00 %
Cellulitis pasteurella	Infections and infestations	1	0.00 %
Central cord syndrome	Injury, poisoning and procedural complications	1	0.00 %
Central nervous system immune reconstitution inflammatory response	Nervous system disorders	1	0.00 %
Central nervous system necrosis	Nervous system disorders	1	0.00 %
Cerebellar embolism	Nervous system disorders	1	0.00 %
Cerebellar tonsillar ectopia	Nervous system disorders	1	0.00 %
Cerebral arteriovenous malformation haemorrhagic	Congenital, familial and genetic disorders	1	0.00 %
Cerebral arteritis	Nervous system disorders	1	0.00 %
Cerebral cavernous malformation	Congenital, familial and genetic disorders	1	0.00 %
Cerebral fungal infection	Infections and infestations	1	0.00 %
Cerebral infarction foetal	Nervous system disorders	1	0.00 %
Cerebral microembolism	Nervous system disorders	1	0.00 %
Cerebrospinal fluid retention	Nervous system disorders	1	0.00 %
Cerebrovascular operation	Surgical and medical procedures	1	0.00 %
Ceruloplasmin increased	Investigations	1	0.00 %
Cervical diathermy	Surgical and medical procedures	1	0.00 %
Cervical dilatation	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Cervix carcinoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cervix dystocia	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Cervix enlargement	Reproductive system and breast disorders	1	0.00 %
Cervix erythema	Reproductive system and breast disorders	1	0.00 %
Cervix haematoma uterine	Reproductive system and breast disorders	1	0.00 %
Cervix injury	Injury, poisoning and procedural complications	1	0.00 %
Cestode infection	Infections and infestations	1	0.00 %
Cheilosis	Gastrointestinal disorders	1	0.00 %
Chemical poisoning	Injury, poisoning and procedural complications	1	0.00 %
Chest scan	Investigations	1	0.00 %
Chest wall cyst	Musculoskeletal and connective tissue disorders	1	0.00 %
Chimerism	Congenital, familial and genetic disorders	1	0.00 %
Chiropractic	Surgical and medical procedures	1	0.00 %
Chloracne	Injury, poisoning and procedural complications	1	0.00 %
Chloroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cholangiosarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cholecystitis chronic	Hepatobiliary disorders	1	0.00 %
Cholecystocholangitis	Hepatobiliary disorders	1	0.00 %
Cholesteatoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Cholesterosis	Metabolism and nutrition disorders	1	0.00 %
Chondrodystrophy	Congenital, familial and genetic disorders	1	0.00 %
Chondroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Chondrosarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Chorioretinal folds	Eye disorders	1	0.00 %
Choroidal detachment	Eye disorders	1	0.00 %
Choroidal haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Choroidal infarction	Eye disorders	1	0.00 %
Chromosome analysis abnormal	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Chronic coronary syndrome	Cardiac disorders	1	0.00 %
Chronic granulomatous disease	Congenital, familial and genetic disorders	1	0.00 %
Chronic hepatitis C	Infections and infestations	1	0.00 %
Chronic hyperplastic eosinophilic sinusitis	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Chronic left ventricular failure	Cardiac disorders	1	0.00 %
Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids	Nervous system disorders	1	0.00 %
Chronic lymphocytic leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Chronic lymphocytic leukaemia stage 0	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Chronic lymphocytic leukaemia transformation	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Chronic myeloid leukaemia recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Chronic paroxysmal hemicrania	Nervous system disorders	1	0.00 %
Chvostek's sign	Metabolism and nutrition disorders	1	0.00 %
Circulating anticoagulant positive	Investigations	1	0.00 %
Circulatory failure neonatal	Vascular disorders	1	0.00 %
Clamping of blood vessel	Surgical and medical procedures	1	0.00 %
Clang associations	Psychiatric disorders	1	0.00 %
Cleft lip	Congenital, familial and genetic disorders	1	0.00 %
Cleft uvula	Congenital, familial and genetic disorders	1	0.00 %
Clinical death	General disorders and administration site conditions	1	0.00 %
Clinomania	Psychiatric disorders	1	0.00 %
Clostridium colitis	Infections and infestations	1	0.00 %
Clot retraction abnormal	Investigations	1	0.00 %
Coagulation disorder neonatal	Blood and lymphatic system disorders	1	0.00 %
Coagulation factor decreased	Investigations	1	0.00 %
Coagulation factor deficiency	Blood and lymphatic system disorders	1	0.00 %
Coagulation factor V level abnormal	Investigations	1	0.00 %
Coagulation factor V level decreased	Investigations	1	0.00 %
Coagulation time	Investigations	1	0.00 %
Coeliac artery aneurysm	Gastrointestinal disorders	1	0.00 %
Coeliac artery compression syndrome	Gastrointestinal disorders	1	0.00 %
Cold agglutinins positive	Investigations	1	0.00 %
Cold dysaesthesia	Nervous system disorders	1	0.00 %
Colectomy	Surgical and medical procedures	1	0.00 %
Colon adenoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Colonoscopy	Investigations	1	0.00 %
Colonoscopy abnormal	Investigations	1	0.00 %
Colonoscopy normal	Investigations	1	0.00 %
Colorectal adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Colostomy	Surgical and medical procedures	1	0.00 %
Colour blindness acquired	Eye disorders	1	0.00 %
Coma scale	Investigations	1	0.00 %
Coma scale normal	Investigations	1	0.00 %
Combined pulmonary fibrosis and emphysema	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Complement factor abnormal	Investigations	1	0.00 %
Complement factor C1 increased	Investigations	1	0.00 %
Complement factor C4 increased	Investigations	1	0.00 %
Complex tic	Psychiatric disorders	1	0.00 %
Compression garment application	Surgical and medical procedures	1	0.00 %
Compulsive handwashing	Psychiatric disorders	1	0.00 %
Compulsive hoarding	Psychiatric disorders	1	0.00 %
Computerised tomogram	Investigations	1	0.00 %
Computerised tomogram abdomen	Investigations	1	0.00 %
Computerised tomogram abdomen abnormal	Investigations	1	0.00 %
Computerised tomogram liver abnormal	Investigations	1	0.00 %
Computerised tomogram normal	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Confabulation	Psychiatric disorders	1	0.00 %
Confluent and reticulate papillomatosis	Skin and subcutaneous tissue disorders	1	0.00 %
Congenital amputation	Congenital, familial and genetic disorders	1	0.00 %
Congenital aortic stenosis	Congenital, familial and genetic disorders	1	0.00 %
Congenital arterial malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital cardiovascular anomaly	Congenital, familial and genetic disorders	1	0.00 %
Congenital cerebrovascular anomaly	Congenital, familial and genetic disorders	1	0.00 %
Congenital cystic lung	Congenital, familial and genetic disorders	1	0.00 %
Congenital cytomegalovirus infection	Congenital, familial and genetic disorders	1	0.00 %
Congenital eye disorder	Congenital, familial and genetic disorders	1	0.00 %
Congenital foot malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital genital malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital haematological disorder	Congenital, familial and genetic disorders	1	0.00 %
Congenital hand malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital hypercoagulation	Congenital, familial and genetic disorders	1	0.00 %
Congenital inguinal hernia	Congenital, familial and genetic disorders	1	0.00 %
Congenital jaw malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital methaemoglobinemia	Congenital, familial and genetic disorders	1	0.00 %
Congenital mitral valve incompetence	Congenital, familial and genetic disorders	1	0.00 %
Congenital myasthenic syndrome	Congenital, familial and genetic disorders	1	0.00 %
Congenital myopathy	Congenital, familial and genetic disorders	1	0.00 %
Congenital neurological degeneration	Congenital, familial and genetic disorders	1	0.00 %
Congenital nose malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital nystagmus	Congenital, familial and genetic disorders	1	0.00 %
Congenital oral malformation	Congenital, familial and genetic disorders	1	0.00 %
Congenital skin dimples	Congenital, familial and genetic disorders	1	0.00 %
Congenital thyroid disorder	Congenital, familial and genetic disorders	1	0.00 %
Congenital tricuspid valve atresia	Congenital, familial and genetic disorders	1	0.00 %
Conjunctival defect	Eye disorders	1	0.00 %
Conjunctival laceration	Injury, poisoning and procedural complications	1	0.00 %
Conjunctival suffusion	Eye disorders	1	0.00 %
Conjunctival telangiectasia	Eye disorders	1	0.00 %
Conjunctival vascular disorder	Eye disorders	1	0.00 %
Constipation neonatal	Gastrointestinal disorders	1	0.00 %
Contact lens intolerance	Eye disorders	1	0.00 %
Contraceptive diaphragm	Surgical and medical procedures	1	0.00 %
Cooling therapy	Surgical and medical procedures	1	0.00 %
Copper deficiency	Metabolism and nutrition disorders	1	0.00 %
Corneal decompensation	Eye disorders	1	0.00 %
Corneal defect	Eye disorders	1	0.00 %
Corneal deposits	Eye disorders	1	0.00 %
Corneal endothelial cell loss	Eye disorders	1	0.00 %
Corneal epithelium defect	Eye disorders	1	0.00 %
Corneal exfoliation	Eye disorders	1	0.00 %
Corneal irritation	Eye disorders	1	0.00 %
Corneal laceration	Injury, poisoning and procedural complications	1	0.00 %
Corneal operation	Surgical and medical procedures	1	0.00 %
Corneal perforation	Eye disorders	1	0.00 %
Corneal pigmentation	Eye disorders	1	0.00 %
Corneal scar	Eye disorders	1	0.00 %
Corneal thinning	Eye disorders	1	0.00 %
Corneal transplant	Surgical and medical procedures	1	0.00 %
Coronary angioplasty	Surgical and medical procedures	1	0.00 %
Coronary artery perforation	Cardiac disorders	1	0.00 %
Coronary bypass thrombosis	Injury, poisoning and procedural complications	1	0.00 %
Coronavirus test negative	Investigations	1	0.00 %
Cortical laminar necrosis	Nervous system disorders	1	0.00 %
Cortisol free urine increased	Investigations	1	0.00 %
COVID-19 prophylaxis	Surgical and medical procedures	1	0.00 %
COVID-19 treatment	Surgical and medical procedures	1	0.00 %
Cranial nerve decompression	Surgical and medical procedures	1	0.00 %
Cranial nerve neoplasm benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Craniofacial fracture	Injury, poisoning and procedural complications	1	0.00 %
Craniotomy	Surgical and medical procedures	1	0.00 %
Creatine urine decreased	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
CREST syndrome	Musculoskeletal and connective tissue disorders	1	0.00 %
Cryoglobulins present	Investigations	1	0.00 %
Cryptococcal meningoencephalitis	Infections and infestations	1	0.00 %
Crystal urine present	Investigations	1	0.00 %
Crystalluria	Renal and urinary disorders	1	0.00 %
CSF cell count decreased	Investigations	1	0.00 %
CSF lymphocyte count abnormal	Investigations	1	0.00 %
CSF mononuclear cell count decreased	Investigations	1	0.00 %
CSF mononuclear cell count increased	Investigations	1	0.00 %
CSF neutrophil count positive	Investigations	1	0.00 %
CSF protein	Investigations	1	0.00 %
CSF protein decreased	Investigations	1	0.00 %
CSF virus identified	Investigations	1	0.00 %
CSF volume decreased	Investigations	1	0.00 %
CSF volume increased	Investigations	1	0.00 %
Cullen's sign	Skin and subcutaneous tissue disorders	1	0.00 %
Culture negative	Investigations	1	0.00 %
Culture positive	Investigations	1	0.00 %
Culture throat	Investigations	1	0.00 %
Culture throat positive	Investigations	1	0.00 %
Cutis laxa	Skin and subcutaneous tissue disorders	1	0.00 %
Cyanosis neonatal	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Cyclic neutropenia	Blood and lymphatic system disorders	1	0.00 %
Cyclitis	Eye disorders	1	0.00 %
CYP2C19 polymorphism	Congenital, familial and genetic disorders	1	0.00 %
Cyst aspiration	Investigations	1	0.00 %
Cyst aspiration abnormal	Investigations	1	0.00 %
Cyst removal	Surgical and medical procedures	1	0.00 %
Cystic fibrosis	Congenital, familial and genetic disorders	1	0.00 %
Cystitis viral	Infections and infestations	1	0.00 %
Cystoscopy	Investigations	1	0.00 %
Cytogenetic analysis abnormal	Investigations	1	0.00 %
Cytokine test	Investigations	1	0.00 %
Cytomegalovirus chorioretinitis	Infections and infestations	1	0.00 %
Cytomegalovirus colitis	Infections and infestations	1	0.00 %
Cytomegalovirus pericarditis	Infections and infestations	1	0.00 %
Cytomegalovirus syndrome	Infections and infestations	1	0.00 %
Decapitation	General disorders and administration site conditions	1	0.00 %
Deep vein thrombosis postoperative	Injury, poisoning and procedural complications	1	0.00 %
Degenerative mitral valve disease	Cardiac disorders	1	0.00 %
Dehiscence	General disorders and administration site conditions	1	0.00 %
Delayed dark adaptation	Eye disorders	1	0.00 %
Delayed delivery	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Delayed ischaemic neurological deficit	Nervous system disorders	1	0.00 %
Dellen	Eye disorders	1	0.00 %
Delusion of grandeur	Psychiatric disorders	1	0.00 %
Dengue haemorrhagic fever	Infections and infestations	1	0.00 %
Dental alveolar anomaly	Gastrointestinal disorders	1	0.00 %
Dental local anaesthesia	Surgical and medical procedures	1	0.00 %
Dental operation	Surgical and medical procedures	1	0.00 %
Dependent personality disorder	Psychiatric disorders	1	0.00 %
Depilation	Surgical and medical procedures	1	0.00 %
Depressive delusion	Psychiatric disorders	1	0.00 %
Dermal filler overcorrection	Injury, poisoning and procedural complications	1	0.00 %
Dermatofibrosarcoma protuberans	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Dermatopathic lymphadenopathy	Blood and lymphatic system disorders	1	0.00 %
Desmoid tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Detached Descemet's membrane	Eye disorders	1	0.00 %
Developmental coordination disorder	Nervous system disorders	1	0.00 %
Developmental hip dysplasia	Congenital, familial and genetic disorders	1	0.00 %
Developmental regression	General disorders and administration site conditions	1	0.00 %
Device defective	Product issues	1	0.00 %
Device delivery system issue	Product issues	1	0.00 %
Device difficult to use	Injury, poisoning and procedural complications	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Device embolisation	General disorders and administration site conditions	1	0.00 %
Device infusion issue	Product issues	1	0.00 %
Device kink	Product issues	1	0.00 %
Device loosening	Product issues	1	0.00 %
Device pacing issue	Product issues	1	0.00 %
Device power source issue	Product issues	1	0.00 %
Device related thrombosis	General disorders and administration site conditions	1	0.00 %
Device stimulation issue	Product issues	1	0.00 %
Device temperature issue	Product issues	1	0.00 %
Diabetic diet	Surgical and medical procedures	1	0.00 %
Diabetic eye disease	Eye disorders	1	0.00 %
Diabetic gangrene	Infections and infestations	1	0.00 %
Diabetic gastroenteropathy	Gastrointestinal disorders	1	0.00 %
Diabetic hyperglycaemic coma	Nervous system disorders	1	0.00 %
Diabetic ketoacidotic hyperglycaemic coma	Nervous system disorders	1	0.00 %
Diabetic retinal oedema	Eye disorders	1	0.00 %
Diabetic ulcer	Skin and subcutaneous tissue disorders	1	0.00 %
Diabetic vascular disorder	Vascular disorders	1	0.00 %
Diabetic wound	Skin and subcutaneous tissue disorders	1	0.00 %
Dialysis hypotension	Vascular disorders	1	0.00 %
Diaphragm neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Diaphragmatic abnormal relaxation	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Diaphragmatic injury	Injury, poisoning and procedural complications	1	0.00 %
Diaphragmatic rupture	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Diastematomyelia	Congenital, familial and genetic disorders	1	0.00 %
Diastrophic dysplasia	Congenital, familial and genetic disorders	1	0.00 %
Diet failure	General disorders and administration site conditions	1	0.00 %
Dieulafoy's vascular malformation	Gastrointestinal disorders	1	0.00 %
Diffuse cutaneous mastocytosis	Skin and subcutaneous tissue disorders	1	0.00 %
Disease propensity	General disorders and administration site conditions	1	0.00 %
Disseminated tuberculosis	Infections and infestations	1	0.00 %
Disseminated varicella	Infections and infestations	1	0.00 %
Disseminated varicella zoster vaccine virus infection	Infections and infestations	1	0.00 %
Dissociative identity disorder	Psychiatric disorders	1	0.00 %
Diverticular fistula	Gastrointestinal disorders	1	0.00 %
Diverticulectomy	Surgical and medical procedures	1	0.00 %
DNA antibody positive	Investigations	1	0.00 %
Documented hypersensitivity to administered product	Injury, poisoning and procedural complications	1	0.00 %
Dolichocolon acquired	Gastrointestinal disorders	1	0.00 %
Double hit lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Double inlet left ventricle	Congenital, familial and genetic disorders	1	0.00 %
Double outlet right ventricle	Congenital, familial and genetic disorders	1	0.00 %
Douglas' abscess	Infections and infestations	1	0.00 %
Drug abuser	Social circumstances	1	0.00 %
Drug administered in wrong device	Injury, poisoning and procedural complications	1	0.00 %
Drug clearance increased	Investigations	1	0.00 %
Drug delivery system malfunction	Product issues	1	0.00 %
Drug dose omission by device	Injury, poisoning and procedural complications	1	0.00 %
Drug ineffective for unapproved indication	General disorders and administration site conditions	1	0.00 %
Drug level abnormal	Investigations	1	0.00 %
Drug level above therapeutic	Investigations	1	0.00 %
Drug level fluctuating	Investigations	1	0.00 %
Drug monitoring procedure not performed	Injury, poisoning and procedural complications	1	0.00 %
Drug withdrawal headache	Nervous system disorders	1	0.00 %
Drug withdrawal syndrome neonatal	General disorders and administration site conditions	1	0.00 %
Drug-device interaction	General disorders and administration site conditions	1	0.00 %
Dry lung syndrome	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Dry skin prophylaxis	Surgical and medical procedures	1	0.00 %
Dumping syndrome	Gastrointestinal disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Duodenal perforation	Gastrointestinal disorders	1	0.00 %
Duodenal rupture	Injury, poisoning and procedural complications	1	0.00 %
Duodenal stenosis	Gastrointestinal disorders	1	0.00 %
Dysglobulinaemia	Blood and lymphatic system disorders	1	0.00 %
Dyskinesia neonatal	Nervous system disorders	1	0.00 %
Dysphonia psychogenic	Psychiatric disorders	1	0.00 %
Dysphotopsis	Injury, poisoning and procedural complications	1	0.00 %
Dysponesis	Musculoskeletal and connective tissue disorders	1	0.00 %
Dysprosody	Nervous system disorders	1	0.00 %
Eagle's syndrome	Musculoskeletal and connective tissue disorders	1	0.00 %
Ear irrigation	Surgical and medical procedures	1	0.00 %
Ear odour	Ear and labyrinth disorders	1	0.00 %
Ear operation	Surgical and medical procedures	1	0.00 %
Ebola disease	Infections and infestations	1	0.00 %
ECG signs of myocardial ischaemia	Investigations	1	0.00 %
Echo virus infection	Infections and infestations	1	0.00 %
Echolalia	Psychiatric disorders	1	0.00 %
Echopraxia	Psychiatric disorders	1	0.00 %
Ectopic pregnancy termination	Surgical and medical procedures	1	0.00 %
Ectopic thyroid	Congenital, familial and genetic disorders	1	0.00 %
Ectrodactyly	Congenital, familial and genetic disorders	1	0.00 %
Edentulous	Social circumstances	1	0.00 %
Egobronchophony	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Ejaculation delayed	Reproductive system and breast disorders	1	0.00 %
Elastofibroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Elbow deformity	Musculoskeletal and connective tissue disorders	1	0.00 %
Electrocardiogram J wave abnormal	Investigations	1	0.00 %
Electrocardiogram J wave increased	Investigations	1	0.00 %
Electrocardiogram QRS complex	Investigations	1	0.00 %
Electrocardiogram QT interval	Investigations	1	0.00 %
Electrocardiogram QT shortened	Investigations	1	0.00 %
Electrocardiogram R on T phenomenon	Investigations	1	0.00 %
Electrocardiogram ST segment	Investigations	1	0.00 %
Electrocardiogram T wave alternans	Investigations	1	0.00 %
Electroconvulsive therapy	Surgical and medical procedures	1	0.00 %
Elliptocytosis hereditary	Congenital, familial and genetic disorders	1	0.00 %
Embolic pneumonia	Infections and infestations	1	0.00 %
Emetophobia	Psychiatric disorders	1	0.00 %
Emotional disorder of childhood	Psychiatric disorders	1	0.00 %
Empty sella syndrome	Endocrine disorders	1	0.00 %
Empyema drainage	Surgical and medical procedures	1	0.00 %
Enamel anomaly	Gastrointestinal disorders	1	0.00 %
Encephalitis califonia	Infections and infestations	1	0.00 %
Encephalitis enteroviral	Infections and infestations	1	0.00 %
Encephalitis lethargica	Infections and infestations	1	0.00 %
Encephalomyelitis viral	Infections and infestations	1	0.00 %
Enchondromatosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Endocardial disease	Cardiac disorders	1	0.00 %
Endocarditis fibroplastica	Cardiac disorders	1	0.00 %
Endocarditis haemophilus	Infections and infestations	1	0.00 %
Endocarditis noninfective	Cardiac disorders	1	0.00 %
Endocervical curettage	Surgical and medical procedures	1	0.00 %
Endocrine neoplasm malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Endocrine test abnormal	Investigations	1	0.00 %
Endometrial ablation	Surgical and medical procedures	1	0.00 %
Endometrial adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Endometrial hypertrophy	Reproductive system and breast disorders	1	0.00 %
Endometrial scratching	Surgical and medical procedures	1	0.00 %
Endotoxic shock	Infections and infestations	1	0.00 %
Enophthalmos	Eye disorders	1	0.00 %
Enostosis	Musculoskeletal and connective tissue disorders	1	0.00 %
Enterobacter bacteraemia	Infections and infestations	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Enterobacter sepsis	Infections and infestations	1	0.00 %
Enterobacter test positive	Investigations	1	0.00 %
Enterococcal bacteraemia	Infections and infestations	1	0.00 %
Enterococcal sepsis	Infections and infestations	1	0.00 %
Enterococcus test positive	Investigations	1	0.00 %
Enterocolitis infectious	Infections and infestations	1	0.00 %
Enterocolitis viral	Infections and infestations	1	0.00 %
Enteropathic spondylitis	Musculoskeletal and connective tissue disorders	1	0.00 %
Enterovirus test positive	Investigations	1	0.00 %
Enzyme activity increased	Investigations	1	0.00 %
Eosinophil percentage abnormal	Investigations	1	0.00 %
Eosinophilic gastritis	Gastrointestinal disorders	1	0.00 %
Eosinophilic pleural effusion	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Epididymal disorder	Reproductive system and breast disorders	1	0.00 %
Epididymal enlargement	Reproductive system and breast disorders	1	0.00 %
Epidural blood patch	Surgical and medical procedures	1	0.00 %
Epidural injection	Surgical and medical procedures	1	0.00 %
Epidural lipomatosis	Nervous system disorders	1	0.00 %
Epileptic psychosis	Psychiatric disorders	1	0.00 %
Epinephrine decreased	Investigations	1	0.00 %
Epiphyseal injury	Injury, poisoning and procedural complications	1	0.00 %
Epiphyses premature fusion	Musculoskeletal and connective tissue disorders	1	0.00 %
Epstein Barr virus positive	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
mucocutaneous ulcer	Investigations	1	0.00 %
Epstein-Barr virus antigen positive	Injury, poisoning and procedural complications	1	0.00 %
Ergot poisoning	Investigations	1	0.00 %
Erysipeloid	Infections and infestations	1	0.00 %
Erythema ab igne	Skin and subcutaneous tissue disorders	1	0.00 %
Erythroblast count abnormal	Investigations	1	0.00 %
Erythroblast count increased	Investigations	1	0.00 %
Erythroplasia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ewing's sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Excessive dietary supplement intake	Surgical and medical procedures	1	0.00 %
Excessive masturbation	Psychiatric disorders	1	0.00 %
Excessive ocular convergence	Eye disorders	1	0.00 %
Excessive sexual fantasies	Psychiatric disorders	1	0.00 %
Exercise adequate	Social circumstances	1	0.00 %
Exercise electrocardiogram	Investigations	1	0.00 %
Exercise electrocardiogram normal	Investigations	1	0.00 %
Exfoliation syndrome	Eye disorders	1	0.00 %
Exhibitionism	Psychiatric disorders	1	0.00 %
Exploratory operation	Surgical and medical procedures	1	0.00 %
Exposure to chemical pollution	Injury, poisoning and procedural complications	1	0.00 %
Exposure to contaminated device	Injury, poisoning and procedural complications	1	0.00 %
Exposure via body fluid	Injury, poisoning and procedural complications	1	0.00 %
Exposure via contaminated device	Injury, poisoning and procedural complications	1	0.00 %
Exposure via father	Injury, poisoning and procedural complications	1	0.00 %
Exposure via partner	Injury, poisoning and procedural complications	1	0.00 %
Exposure via unknown route	Injury, poisoning and procedural complications	1	0.00 %
Extramedullary haemopoiesis	Blood and lymphatic system disorders	1	0.00 %
Exudative retinopathy	Eye disorders	1	0.00 %
Eye haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Eye infection staphylococcal	Infections and infestations	1	0.00 %
Eyeglasses therapy	Surgical and medical procedures	1	0.00 %
Eyelid abrasion	Injury, poisoning and procedural complications	1	0.00 %
Face and mouth X-ray	Investigations	1	0.00 %
Face lift	Surgical and medical procedures	1	0.00 %
Face presentation	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Factor IX deficiency	Congenital, familial and genetic disorders	1	0.00 %
Factor IX inhibition	Blood and lymphatic system disorders	1	0.00 %
Factor V Leiden carrier	Congenital, familial and genetic disorders	1	0.00 %
Factor VII deficiency	Congenital, familial and genetic disorders	1	0.00 %
Factor XI deficiency	Congenital, familial and genetic disorders	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Factor XIII deficiency	Congenital, familial and genetic disorders	1	0.00 %
Faecal calprotectin	Investigations	1	0.00 %
Faecal fat increased	Investigations	1	0.00 %
Fallopian tube abscess	Infections and infestations	1	0.00 %
Fallopian tube cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Fallopian tube neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Fallopian tube perforation	Injury, poisoning and procedural complications	1	0.00 %
False lumen dilatation of aortic dissection	Vascular disorders	1	0.00 %
False negative investigation result	Investigations	1	0.00 %
False positive tuberculosis test	Investigations	1	0.00 %
Fascial infection	Infections and infestations	1	0.00 %
Fasciectomy	Surgical and medical procedures	1	0.00 %
Fat embolism	Injury, poisoning and procedural complications	1	0.00 %
Fat intolerance	Metabolism and nutrition disorders	1	0.00 %
Fatty liver alcoholic	Hepatobiliary disorders	1	0.00 %
Fear of closed spaces	Psychiatric disorders	1	0.00 %
Febrile infection-related epilepsy syndrome	Nervous system disorders	1	0.00 %
Female sexual arousal disorder	Reproductive system and breast disorders	1	0.00 %
Femoral nerve palsy	Nervous system disorders	1	0.00 %
Femoral pulse	Investigations	1	0.00 %
Femoroacetabular impingement	Musculoskeletal and connective tissue disorders	1	0.00 %
Fibrin	Investigations	1	0.00 %
Fibrinolysis abnormal	Investigations	1	0.00 %
Fibroblast growth factor 23	Investigations	1	0.00 %
Fibroblast growth factor 23 increased	Investigations	1	0.00 %
Fibrodysplasia ossificans progressiva	Congenital, familial and genetic disorders	1	0.00 %
Fibromatosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Finger repair operation	Surgical and medical procedures	1	0.00 %
First bite syndrome	General disorders and administration site conditions	1	0.00 %
Flagellate dermatitis	Skin and subcutaneous tissue disorders	1	0.00 %
Flooding	Social circumstances	1	0.00 %
Fluctuance	Musculoskeletal and connective tissue disorders	1	0.00 %
Fluid replacement	Surgical and medical procedures	1	0.00 %
Foetal anaemia	Blood and lymphatic system disorders	1	0.00 %
Foetal arrhythmia	Cardiac disorders	1	0.00 %
Foetal damage	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Foetal exposure timing unspecified	Injury, poisoning and procedural complications	1	0.00 %
Foetal heart rate acceleration abnormality	Cardiac disorders	1	0.00 %
Foetal heart rate disorder	Cardiac disorders	1	0.00 %
Foetal malnutrition	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Foetal malpresentation	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Foetal monitoring	Investigations	1	0.00 %
Foetal non-stress test	Investigations	1	0.00 %
Foetal non-stress test abnormal	Investigations	1	0.00 %
Foetal renal impairment	Renal and urinary disorders	1	0.00 %
Follicle centre lymphoma, follicular grade I, II, III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Follicular cystitis	Renal and urinary disorders	1	0.00 %
Follicular eczema	Skin and subcutaneous tissue disorders	1	0.00 %
Follicular lymphoma stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Follicular lymphoma stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Follicular lymphoma stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Follicular mucinosis	Skin and subcutaneous tissue disorders	1	0.00 %
Fontanelle bulging	Nervous system disorders	1	0.00 %
Fontanelle depressed	Nervous system disorders	1	0.00 %
Foramen magnum stenosis	Congenital, familial and genetic disorders	1	0.00 %
Forced expiratory flow	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Forced expiratory flow decreased	Investigations	1	0.00 %
Forced expiratory volume abnormal	Investigations	1	0.00 %
Forced expiratory volume decreased	Investigations	1	0.00 %
Forced vital capacity decreased	Investigations	1	0.00 %
Forceps delivery	Surgical and medical procedures	1	0.00 %
Foreign body in ear	Injury, poisoning and procedural complications	1	0.00 %
Foreign body in mouth	Injury, poisoning and procedural complications	1	0.00 %
Foreign body in urogenital tract	Injury, poisoning and procedural complications	1	0.00 %
Foreskin oedema	Reproductive system and breast disorders	1	0.00 %
Foveal reflex abnormal	Investigations	1	0.00 %
Fractional exhaled nitric oxide abnormal	Investigations	1	0.00 %
Fractional exhaled nitric oxide normal	Investigations	1	0.00 %
Fracture blisters	Skin and subcutaneous tissue disorders	1	0.00 %
Fracture reduction	Surgical and medical procedures	1	0.00 %
Fractured skull depressed	Injury, poisoning and procedural complications	1	0.00 %
Free prostate-specific antigen increased	Investigations	1	0.00 %
Free thyroxine index decreased	Investigations	1	0.00 %
Friedreich's ataxia	Congenital, familial and genetic disorders	1	0.00 %
Fungal balanitis	Infections and infestations	1	0.00 %
Fungal peritonitis	Infections and infestations	1	0.00 %
Fungal rhinitis	Infections and infestations	1	0.00 %
Fungating wound	Skin and subcutaneous tissue disorders	1	0.00 %
Funguria	Infections and infestations	1	0.00 %
Gadolinium deposition disease	Injury, poisoning and procedural complications	1	0.00 %
Gallbladder adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gallbladder cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gallbladder cholesterolosis	Hepatobiliary disorders	1	0.00 %
Gallbladder hypofunction	Hepatobiliary disorders	1	0.00 %
Gallbladder obstruction	Hepatobiliary disorders	1	0.00 %
Gallbladder rupture	Hepatobiliary disorders	1	0.00 %
Gamma-glutamyltransferase	Investigations	1	0.00 %
Ganglioneuroma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gas gangrene	Infections and infestations	1	0.00 %
Gastric cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gastric fibrosis	Gastrointestinal disorders	1	0.00 %
Gastric haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gastric hypermotility	Gastrointestinal disorders	1	0.00 %
Gastric hypomotility	Gastrointestinal disorders	1	0.00 %
Gastric neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gastric pH	Investigations	1	0.00 %
Gastric stenosis	Gastrointestinal disorders	1	0.00 %
Gastric ulcer helicobacter	Infections and infestations	1	0.00 %
Gastric ulcer perforation	Gastrointestinal disorders	1	0.00 %
Gastritis herpes	Infections and infestations	1	0.00 %
Gastritis hypertrophic	Gastrointestinal disorders	1	0.00 %
Gastroenteritis adenovirus	Infections and infestations	1	0.00 %
Gastrointestinal adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gastrointestinal angiodysplasia	Gastrointestinal disorders	1	0.00 %
Gastrointestinal cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gastrointestinal fistula	Gastrointestinal disorders	1	0.00 %
Gastrointestinal malformation	Congenital, familial and genetic disorders	1	0.00 %
Gastrointestinal polyp haemorrhage	Gastrointestinal disorders	1	0.00 %
Gastrointestinal scan	Investigations	1	0.00 %
Gastrointestinal stoma output increased	Investigations	1	0.00 %
Gastrointestinal stromal tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gastrointestinal surgery	Surgical and medical procedures	1	0.00 %
Gastrointestinal wall thinning	Gastrointestinal disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Gastropexy	Surgical and medical procedures	1	0.00 %
Gastrorrhaphy	Surgical and medical procedures	1	0.00 %
Gelastic seizure	Nervous system disorders	1	0.00 %
Gender dysphoria	Psychiatric disorders	1	0.00 %
General anaesthesia	Surgical and medical procedures	1	0.00 %
General physical condition normal	Investigations	1	0.00 %
Geniculate ganglionitis	Nervous system disorders	1	0.00 %
Genital anaesthesia	Reproductive system and breast disorders	1	0.00 %
Genital contusion	Injury, poisoning and procedural complications	1	0.00 %
Genital cyst	Reproductive system and breast disorders	1	0.00 %
Genital macule	Reproductive system and breast disorders	1	0.00 %
Gerstmann's syndrome	Nervous system disorders	1	0.00 %
Gestational trophoblastic tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Giant cell myocarditis	Cardiac disorders	1	0.00 %
Giant cell tumour of tendon sheath	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Gingival cyst	Gastrointestinal disorders	1	0.00 %
Glabellar reflex abnormal	Nervous system disorders	1	0.00 %
Globulins decreased	Investigations	1	0.00 %
Glomerulonephritis proliferative	Renal and urinary disorders	1	0.00 %
Glossopharyngeal nerve paralysis	Nervous system disorders	1	0.00 %
Glottal incompetence	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Glucocorticoids abnormal	Investigations	1	0.00 %
Glucose tolerance impaired in pregnancy	Metabolism and nutrition disorders	1	0.00 %
Glucose tolerance increased	Investigations	1	0.00 %
Glutamate dehydrogenase decreased	Investigations	1	0.00 %
Glutathione s-transferase decreased	Investigations	1	0.00 %
Glycogen storage disorder	Congenital, familial and genetic disorders	1	0.00 %
Glycolysis increased	Investigations	1	0.00 %
Glycopenia	Metabolism and nutrition disorders	1	0.00 %
Good syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Graft complication	Injury, poisoning and procedural complications	1	0.00 %
Graft versus host disease in eye	Immune system disorders	1	0.00 %
Grandiosity	Psychiatric disorders	1	0.00 %
Granulocyte percentage decreased	Investigations	1	0.00 %
Granulocyte percentage increased	Investigations	1	0.00 %
Granulocytosis	Blood and lymphatic system disorders	1	0.00 %
Granulomatous pneumonitis	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Great saphenous vein closure	Surgical and medical procedures	1	0.00 %
Grey matter heterotopia	Congenital, familial and genetic disorders	1	0.00 %
Growth of eyelashes	Eye disorders	1	0.00 %
Growth retardation	Musculoskeletal and connective tissue disorders	1	0.00 %
Gun shot wound	Injury, poisoning and procedural complications	1	0.00 %
Gustometry	Investigations	1	0.00 %
H1N1 influenza	Infections and infestations	1	0.00 %
Haemangioma of bone	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Haemangiopericytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Haematidrosis	Skin and subcutaneous tissue disorders	1	0.00 %
Haematinuria	Renal and urinary disorders	1	0.00 %
Haematocoele	Vascular disorders	1	0.00 %
Haematological malignancy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Haematoma evacuation	Surgical and medical procedures	1	0.00 %
Haematosalpinx	Reproductive system and breast disorders	1	0.00 %
Haematotympanum	Ear and labyrinth disorders	1	0.00 %
Haemodynamic rebound	Vascular disorders	1	0.00 %
Haemoglobin	Investigations	1	0.00 %
Haemoglobin distribution width increased	Investigations	1	0.00 %
Haemolytic transfusion reaction	Injury, poisoning and procedural complications	1	0.00 %
Haemorrhage foetal	Pregnancy, puerperium and perinatal conditions	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Haemorrhagic arteriovenous malformation	Congenital, familial and genetic disorders	1	0.00 %
Haemorrhagic ascites	Gastrointestinal disorders	1	0.00 %
Haemorrhagic cerebellar infarction	Nervous system disorders	1	0.00 %
Haemorrhagic fever with renal syndrome	Infections and infestations	1	0.00 %
Haemorrhagic necrotic pancreatitis	Gastrointestinal disorders	1	0.00 %
Haemorrhagic varicella syndrome	Infections and infestations	1	0.00 %
Haemorrhoid infection	Infections and infestations	1	0.00 %
Hair growth rate abnormal	Skin and subcutaneous tissue disorders	1	0.00 %
Hairy cell leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Hand amputation	Surgical and medical procedures	1	0.00 %
Hanging	General disorders and administration site conditions	1	0.00 %
Hangnail	Skin and subcutaneous tissue disorders	1	0.00 %
Hashimoto's encephalopathy	Nervous system disorders	1	0.00 %
Hearing aid user	Social circumstances	1	0.00 %
Heat therapy	Surgical and medical procedures	1	0.00 %
Heavy exposure to ultraviolet light	Injury, poisoning and procedural complications	1	0.00 %
Heavy metal abnormal	Investigations	1	0.00 %
Heavy metal increased	Investigations	1	0.00 %
Helicobacter test	Investigations	1	0.00 %
Heliotrope rash	Skin and subcutaneous tissue disorders	1	0.00 %
Hemiasomatognosia	Nervous system disorders	1	0.00 %
Hepatic artery embolism	Hepatobiliary disorders	1	0.00 %
Hepatic atrophy	Hepatobiliary disorders	1	0.00 %
Hepatic calcification	Hepatobiliary disorders	1	0.00 %
Hepatic cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Hepatic enzyme	Investigations	1	0.00 %
Hepatic haematoma	Hepatobiliary disorders	1	0.00 %
Hepatic ischaemia	Hepatobiliary disorders	1	0.00 %
Hepatic rupture	Injury, poisoning and procedural complications	1	0.00 %
Hepatic vein dilatation	Hepatobiliary disorders	1	0.00 %
Hepatic vein occlusion	Hepatobiliary disorders	1	0.00 %
Hepatitis A antibody abnormal	Investigations	1	0.00 %
Hepatitis B antibody abnormal	Investigations	1	0.00 %
Hepatitis B antibody positive	Investigations	1	0.00 %
Hepatitis B core antibody positive	Investigations	1	0.00 %
Hepatitis B test negative	Investigations	1	0.00 %
Hepatitis B virus test positive	Investigations	1	0.00 %
Hepatitis chronic active	Hepatobiliary disorders	1	0.00 %
Hepatitis D	Infections and infestations	1	0.00 %
Hepatobiliary cyst	Hepatobiliary disorders	1	0.00 %
Hepatobiliary disease	Hepatobiliary disorders	1	0.00 %
HER2 positive breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Herbal interaction	General disorders and administration site conditions	1	0.00 %
Hereditary angioedema with normal C1 esterase inhibitor	Congenital, familial and genetic disorders	1	0.00 %
Hereditary optic atrophy	Congenital, familial and genetic disorders	1	0.00 %
Herpes simplex gastritis	Infections and infestations	1	0.00 %
Herpes simplex pharyngitis	Infections and infestations	1	0.00 %
Herpes simplex viraemia	Infections and infestations	1	0.00 %
Herpes virus test	Investigations	1	0.00 %
Herpes zoster meningomyelitis	Infections and infestations	1	0.00 %
Herpes zoster necrotising retinopathy	Infections and infestations	1	0.00 %
Heteronymous diplopia	Eye disorders	1	0.00 %
Hiatus hernia strangulated	Gastrointestinal disorders	1	0.00 %
High density lipoprotein	Investigations	1	0.00 %
High-grade B-cell lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Histone antibody positive	Investigations	1	0.00 %
Histrionic personality disorder	Psychiatric disorders	1	0.00 %
HIV antibody	Investigations	1	0.00 %
HIV peripheral neuropathy	Infections and infestations	1	0.00 %
HIV test	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
HIV test negative	Investigations	1	0.00 %
Hodgkin's disease mixed cellularity stage unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Hodgkin's disease stage II	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Homans' sign	Investigations	1	0.00 %
Homocystinaemia	Congenital, familial and genetic disorders	1	0.00 %
Hoover's sign of leg paresis	Investigations	1	0.00 %
Hormonal contraception	Surgical and medical procedures	1	0.00 %
Hormone receptor positive breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Huerthle cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Human chorionic gonadotropin abnormal	Investigations	1	0.00 %
Human ehrlichiosis	Infections and infestations	1	0.00 %
Human herpes virus 6 serology positive	Investigations	1	0.00 %
Human herpesvirus 6 encephalitis	Infections and infestations	1	0.00 %
Human herpesvirus 7 infection	Infections and infestations	1	0.00 %
Human metapneumovirus test positive	Investigations	1	0.00 %
Human papilloma virus test negative	Investigations	1	0.00 %
Human seminal plasma hypersensitivity	Immune system disorders	1	0.00 %
Humidity intolerance	General disorders and administration site conditions	1	0.00 %
Humoral immune defect	Immune system disorders	1	0.00 %
Hydranencephaly	Congenital, familial and genetic disorders	1	0.00 %
Hydroxyapatite crystal deposition disease	Musculoskeletal and connective tissue disorders	1	0.00 %
Hyper IgD syndrome	Congenital, familial and genetic disorders	1	0.00 %
Hyperadrenocorticism	Endocrine disorders	1	0.00 %
Hyperalbuminaemia	Metabolism and nutrition disorders	1	0.00 %
Hyperammonaemic encephalopathy	Nervous system disorders	1	0.00 %
Hypercalcaemia of malignancy	Endocrine disorders	1	0.00 %
Hypercarotinaemia	Metabolism and nutrition disorders	1	0.00 %
Hypercatabolism	Metabolism and nutrition disorders	1	0.00 %
Hypercreatininaemia	Musculoskeletal and connective tissue disorders	1	0.00 %
Hyperinsulinaemic hypoglycaemia	Metabolism and nutrition disorders	1	0.00 %
Hypermagnesaemia	Metabolism and nutrition disorders	1	0.00 %
Hyperoestrogenism	Endocrine disorders	1	0.00 %
Hyperparathyroidism secondary	Endocrine disorders	1	0.00 %
Hyperplasia of thymic epithelium	Blood and lymphatic system disorders	1	0.00 %
Hyperprothrombinaemia	Blood and lymphatic system disorders	1	0.00 %
Hypersplenism	Blood and lymphatic system disorders	1	0.00 %
Hypertensive hydrocephalus	Nervous system disorders	1	0.00 %
Hyperviscosity syndrome	Blood and lymphatic system disorders	1	0.00 %
Hypervitaminosis	Metabolism and nutrition disorders	1	0.00 %
Hypervitaminosis B	Metabolism and nutrition disorders	1	0.00 %
Hypochondroplasia	Congenital, familial and genetic disorders	1	0.00 %
Hypoglossal nerve paresis	Nervous system disorders	1	0.00 %
Hypoglycaemic seizure	Nervous system disorders	1	0.00 %
Hypokinetic dysarthria	Nervous system disorders	1	0.00 %
Hypophonesis	Investigations	1	0.00 %
Hypophosphatasia	Congenital, familial and genetic disorders	1	0.00 %
Hypoprothrombinaemia	Blood and lymphatic system disorders	1	0.00 %
Hypopyon	Infections and infestations	1	0.00 %
Hypothermia neonatal	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Hypotony of eye	Eye disorders	1	0.00 %
Hypozincaemia	Metabolism and nutrition disorders	1	0.00 %
Hysteroscopy	Investigations	1	0.00 %
Ichthyosis	Congenital, familial and genetic disorders	1	0.00 %
Idiopathic CD4 lymphocytopenia	Blood and lymphatic system disorders	1	0.00 %
Idiopathic interstitial pneumonia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Idiopathic neutropenia	Blood and lymphatic system disorders	1	0.00 %
Ileal perforation	Gastrointestinal disorders	1	0.00 %
Ileectomy	Surgical and medical procedures	1	0.00 %
Ileostomy	Surgical and medical procedures	1	0.00 %
Iliac artery rupture	Vascular disorders	1	0.00 %
Iliac bruit	Investigations	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Illogical thinking	Psychiatric disorders	1	0.00 %
Imaging procedure artifact	Investigations	1	0.00 %
Immune reconstitution inflammatory syndrome associated tuberculosis	Infections and infestations	1	0.00 %
Immune-mediated cholangitis	Hepatobiliary disorders	1	0.00 %
Immune-mediated cystitis	Renal and urinary disorders	1	0.00 %
Immune-mediated dermatitis	Skin and subcutaneous tissue disorders	1	0.00 %
Immune-mediated hypothyroidism	Endocrine disorders	1	0.00 %
Immunosuppressant drug level decreased	Investigations	1	0.00 %
Imperforate oesophagus	Congenital, familial and genetic disorders	1	0.00 %
Implant site dermatitis	General disorders and administration site conditions	1	0.00 %
Implant site haemorrhage	General disorders and administration site conditions	1	0.00 %
Implant site irritation	General disorders and administration site conditions	1	0.00 %
Implant site paraesthesia	General disorders and administration site conditions	1	0.00 %
Implant site rash	General disorders and administration site conditions	1	0.00 %
Implant site urticaria	General disorders and administration site conditions	1	0.00 %
Inadequate lubrication	Reproductive system and breast disorders	1	0.00 %
Inappropriate schedule of product discontinuation	Injury, poisoning and procedural complications	1	0.00 %
Inborn error of metabolism	Congenital, familial and genetic disorders	1	0.00 %
Incarcerated umbilical hernia	Gastrointestinal disorders	1	0.00 %
Incision site abscess	Infections and infestations	1	0.00 %
Incision site discharge	Injury, poisoning and procedural complications	1	0.00 %
Incision site haemorrhage	Injury, poisoning and procedural complications	1	0.00 %
Incision site impaired healing	Injury, poisoning and procedural complications	1	0.00 %
Incision site pruritus	Injury, poisoning and procedural complications	1	0.00 %
Incorrect product dosage form administered	Injury, poisoning and procedural complications	1	0.00 %
Indeterminate leprosy	Infections and infestations	1	0.00 %
Induced abortion failed	Injury, poisoning and procedural complications	1	0.00 %
Induced abortion haemorrhage	Injury, poisoning and procedural complications	1	0.00 %
Infant	Social circumstances	1	0.00 %
Infantile spitting up	Gastrointestinal disorders	1	0.00 %
Infected bunion	Infections and infestations	1	0.00 %
Infected fistula	Infections and infestations	1	0.00 %
Infected neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Infected vasculitis	Infections and infestations	1	0.00 %
Infection protozoal	Infections and infestations	1	0.00 %
Infection via vaccinee	Infections and infestations	1	0.00 %
Infective aneurysm	Infections and infestations	1	0.00 %
Infective spondylitis	Infections and infestations	1	0.00 %
Infective uveitis	Infections and infestations	1	0.00 %
Inferior vena cava stenosis	Vascular disorders	1	0.00 %
Inferiority complex	Psychiatric disorders	1	0.00 %
Inflammation scan	Investigations	1	0.00 %
Inflammatory marker test	Investigations	1	0.00 %
Inflammatory pseudotumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Influenza B virus test positive	Investigations	1	0.00 %
Infusion	Surgical and medical procedures	1	0.00 %
Infusion site haematoma	General disorders and administration site conditions	1	0.00 %
Infusion site hypoesthesia	General disorders and administration site conditions	1	0.00 %
Infusion site induration	General disorders and administration site conditions	1	0.00 %
Infusion site infection	Infections and infestations	1	0.00 %
Infusion site lymphadenopathy	General disorders and administration site conditions	1	0.00 %
Infusion site mass	General disorders and administration site conditions	1	0.00 %
Infusion site paraesthesia	General disorders and administration site conditions	1	0.00 %
Infusion site reaction	General disorders and administration site conditions	1	0.00 %
Infusion site streaking	General disorders and administration site conditions	1	0.00 %
Infusion site urticaria	General disorders and administration site conditions	1	0.00 %
Inguinal hernia repair	Surgical and medical procedures	1	0.00 %
Injection site abscess	Infections and infestations	1	0.00 %
Injection site alopecia	General disorders and administration site conditions	1	0.00 %
Injection site hypertrophy	General disorders and administration site conditions	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Injection site injury	General disorders and administration site conditions	1	0.00 %
Injection site joint discomfort	General disorders and administration site conditions	1	0.00 %
Injection site joint inflammation	General disorders and administration site conditions	1	0.00 %
Injection site papule	General disorders and administration site conditions	1	0.00 %
Injection site pustule	Infections and infestations	1	0.00 %
Injection site thrombosis	General disorders and administration site conditions	1	0.00 %
Injury of conjunctiva	Injury, poisoning and procedural complications	1	0.00 %
Instillation site haemorrhage	General disorders and administration site conditions	1	0.00 %
Instillation site hyperaesthesia	General disorders and administration site conditions	1	0.00 %
Insulin therapy	Surgical and medical procedures	1	0.00 %
Insulin tolerance test abnormal	Investigations	1	0.00 %
Insulin-requiring type 2 diabetes mellitus	Metabolism and nutrition disorders	1	0.00 %
Intelligence increased	Nervous system disorders	1	0.00 %
Intelligence test	Investigations	1	0.00 %
Intensive care unit acquired weakness	Nervous system disorders	1	0.00 %
Intentional device use issue	Injury, poisoning and procedural complications	1	0.00 %
Intercepted product administration error	Injury, poisoning and procedural complications	1	0.00 %
Intercepted product selection error	Injury, poisoning and procedural complications	1	0.00 %
Intercepted product storage error	Injury, poisoning and procedural complications	1	0.00 %
Intermittent explosive disorder	Psychiatric disorders	1	0.00 %
Internal fixation of fracture	Surgical and medical procedures	1	0.00 %
Internal fixation of spine	Surgical and medical procedures	1	0.00 %
Interspinous osteoarthritis	Musculoskeletal and connective tissue disorders	1	0.00 %
Interventricular septum rupture	Cardiac disorders	1	0.00 %
Intervertebral disc displacement	Musculoskeletal and connective tissue disorders	1	0.00 %
Intervertebral disc operation	Surgical and medical procedures	1	0.00 %
Intestinal adenocarcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Intestinal anastomosis	Surgical and medical procedures	1	0.00 %
Intestinal angina	Gastrointestinal disorders	1	0.00 %
Intestinal fibrosis	Gastrointestinal disorders	1	0.00 %
Intestinal fistula	Gastrointestinal disorders	1	0.00 %
Intestinal gangrene	Infections and infestations	1	0.00 %
Intestinal mucosal tear	Gastrointestinal disorders	1	0.00 %
Intestinal operation	Surgical and medical procedures	1	0.00 %
Intestinal transit time increased	Investigations	1	0.00 %
Intestinal vascular disorder	Gastrointestinal disorders	1	0.00 %
Intra-cerebral aneurysm operation	Surgical and medical procedures	1	0.00 %
Intra-uterine contraceptive device removal	Surgical and medical procedures	1	0.00 %
Intracardiac mass	Cardiac disorders	1	0.00 %
Intracranial lipoma	Congenital, familial and genetic disorders	1	0.00 %
Intraductal papilloma of breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Intravesical immunotherapy	Surgical and medical procedures	1	0.00 %
Invasive breast carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Investigation	Investigations	1	0.00 %
Iodine allergy	Immune system disorders	1	0.00 %
Iodine uptake increased	Investigations	1	0.00 %
Iridocele	Eye disorders	1	0.00 %
Iridotomy	Surgical and medical procedures	1	0.00 %
Iris cyst	Eye disorders	1	0.00 %
Iris neovascularisation	Eye disorders	1	0.00 %
Iron binding capacity total abnormal	Investigations	1	0.00 %
Iron binding capacity total decreased	Investigations	1	0.00 %
Iron binding capacity total increased	Investigations	1	0.00 %
Ischaemic enteritis	Gastrointestinal disorders	1	0.00 %
Isodicentric chromosome 15 syndrome	Congenital, familial and genetic disorders	1	0.00 %
Isoimmune haemolytic disease	Blood and lymphatic system disorders	1	0.00 %
IVth nerve injury	Injury, poisoning and procedural complications	1	0.00 %
Janeway lesion	Infections and infestations	1	0.00 %
Japanese spotted fever	Infections and infestations	1	0.00 %
Jejunal perforation	Gastrointestinal disorders	1	0.00 %
Job change	Social circumstances	1	0.00 %
Joint fluid drainage	Surgical and medical procedures	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Joint neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Joint position sense decreased	Investigations	1	0.00 %
Jugular vein embolism	Vascular disorders	1	0.00 %
Jugular vein haemorrhage	Vascular disorders	1	0.00 %
Juvenile polymyositis	Musculoskeletal and connective tissue disorders	1	0.00 %
Juvenile psoriatic arthritis	Musculoskeletal and connective tissue disorders	1	0.00 %
Kaposi's sarcoma AIDS related	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Kearns-Sayre syndrome	Congenital, familial and genetic disorders	1	0.00 %
Keratitis bacterial	Infections and infestations	1	0.00 %
Keratoplasty	Surgical and medical procedures	1	0.00 %
Kernig's sign	Nervous system disorders	1	0.00 %
Kidney contusion	Injury, poisoning and procedural complications	1	0.00 %
Kidney hypermobility	Renal and urinary disorders	1	0.00 %
Kinesiophobia	Psychiatric disorders	1	0.00 %
Klippel-Trenaunay syndrome	Congenital, familial and genetic disorders	1	0.00 %
Koilonychia	Skin and subcutaneous tissue disorders	1	0.00 %
Labelled drug-drug interaction medication error	Injury, poisoning and procedural complications	1	0.00 %
Laboratory test normal	Investigations	1	0.00 %
Lacrimal structural disorder	Eye disorders	1	0.00 %
Lactate dehydrogenase urine increased	Investigations	1	0.00 %
Lactobacillus infection	Infections and infestations	1	0.00 %
Lactobacillus test positive	Investigations	1	0.00 %
Laparoscopy abnormal	Investigations	1	0.00 %
Large for dates baby	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Large granular lymphocytosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Large intestinal polypectomy	Surgical and medical procedures	1	0.00 %
Large intestine benign neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Large intestine erosion	Gastrointestinal disorders	1	0.00 %
Laryngeal atrophy	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Laryngeal cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Laryngeal injury	Injury, poisoning and procedural complications	1	0.00 %
Laryngeal tremor	Nervous system disorders	1	0.00 %
Laryngeal ulceration	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Laryngitis bacterial	Infections and infestations	1	0.00 %
Laryngoscopy	Investigations	1	0.00 %
Laryngotracheal oedema	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Latent tuberculosis	Infections and infestations	1	0.00 %
Lead dislodgement	Product issues	1	0.00 %
Left-to-right cardiac shunt	Congenital, familial and genetic disorders	1	0.00 %
Lemierre syndrome	Infections and infestations	1	0.00 %
Lennox-Gastaut syndrome	Nervous system disorders	1	0.00 %
Lens extraction	Surgical and medical procedures	1	0.00 %
Lenticular injury	Injury, poisoning and procedural complications	1	0.00 %
Lentigo	Skin and subcutaneous tissue disorders	1	0.00 %
Lepromatous leprosy	Infections and infestations	1	0.00 %
Leptospirosis	Infections and infestations	1	0.00 %
Leukaemic infiltration	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Leukaemic lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Leukaemoid reaction	Blood and lymphatic system disorders	1	0.00 %
Leukocyte alkaline phosphatase increased	Investigations	1	0.00 %
Leukocyte vacuolisation	Blood and lymphatic system disorders	1	0.00 %
Levator syndrome	Gastrointestinal disorders	1	0.00 %
Lid margin discharge	Eye disorders	1	0.00 %
Ligament operation	Surgical and medical procedures	1	0.00 %
Light chain analysis abnormal	Investigations	1	0.00 %
Limb hypoplasia congenital	Congenital, familial and genetic disorders	1	0.00 %
Limited symptom panic attack	Psychiatric disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Lip and/or oral cavity cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Lip cosmetic procedure	Surgical and medical procedures	1	0.00 %
Lip infection	Infections and infestations	1	0.00 %
Lipids	Investigations	1	0.00 %
Lipodystrophy acquired	Skin and subcutaneous tissue disorders	1	0.00 %
Lipogranuloma	General disorders and administration site conditions	1	0.00 %
Lipoprotein increased	Investigations	1	0.00 %
Liver carcinoma ruptured	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Liver function test	Investigations	1	0.00 %
Liver palpable	Investigations	1	0.00 %
Liver sarcoidosis	Hepatobiliary disorders	1	0.00 %
Liver scan	Investigations	1	0.00 %
Liver scan abnormal	Investigations	1	0.00 %
Localised alternating hot and cold therapy	Surgical and medical procedures	1	0.00 %
Lochial infection	Infections and infestations	1	0.00 %
Long QT syndrome congenital	Congenital, familial and genetic disorders	1	0.00 %
Loss of dreaming	Psychiatric disorders	1	0.00 %
Low density lipoprotein	Investigations	1	0.00 %
Low set ears	Congenital, familial and genetic disorders	1	0.00 %
Lower limb artery perforation	Vascular disorders	1	0.00 %
Lumbosacral radiculoplexus neuropathy	Nervous system disorders	1	0.00 %
Lung adenocarcinoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Lung adenocarcinoma stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Lung carcinoma cell type unspecified stage 0	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Lung carcinoma cell type unspecified stage I	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Lung diffusion test decreased	Investigations	1	0.00 %
Lung hernia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Lung operation	Surgical and medical procedures	1	0.00 %
Lung perforation	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Lung transplant	Surgical and medical procedures	1	0.00 %
Lupus endocarditis	Cardiac disorders	1	0.00 %
Lupus myositis	Musculoskeletal and connective tissue disorders	1	0.00 %
Lymph node calcification	Blood and lymphatic system disorders	1	0.00 %
Lymph node rupture	Blood and lymphatic system disorders	1	0.00 %
Lymph node ulcer	Blood and lymphatic system disorders	1	0.00 %
Lymphadenocyst	Blood and lymphatic system disorders	1	0.00 %
Lymphocytic hypophysitis	Endocrine disorders	1	0.00 %
Lymphocytic leukaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Macroamylasaemia	Metabolism and nutrition disorders	1	0.00 %
Macrocephaly	Congenital, familial and genetic disorders	1	0.00 %
Macrosomia	General disorders and administration site conditions	1	0.00 %
Macular cherry-red spots	Eye disorders	1	0.00 %
Macular fibrosis	Eye disorders	1	0.00 %
Macular opacity	Eye disorders	1	0.00 %
Macular scar	Eye disorders	1	0.00 %
Magnetic resonance imaging abdominal	Investigations	1	0.00 %
Magnetic resonance imaging breast abnormal	Investigations	1	0.00 %
Magnetic therapy	Surgical and medical procedures	1	0.00 %
Malaria relapse	Infections and infestations	1	0.00 %
Male genital examination abnormal	Investigations	1	0.00 %
Male orgasmic disorder	Psychiatric disorders	1	0.00 %
Male sexual dysfunction	Reproductive system and breast disorders	1	0.00 %
Malformation venous	Congenital, familial and genetic disorders	1	0.00 %
Malignant dysphagia	Gastrointestinal disorders	1	0.00 %
Malignant lymphoid neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Malignant neoplasm of eye	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Malignant neoplasm of renal pelvis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Malignant neoplasm of unknown primary site	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Malignant oligodendrogioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Malignant splenic neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Mallet finger	Injury, poisoning and procedural complications	1	0.00 %
Mammoplasty	Surgical and medical procedures	1	0.00 %
Manic symptom	Psychiatric disorders	1	0.00 %
Marital problem	Social circumstances	1	0.00 %
Masked fever	General disorders and administration site conditions	1	0.00 %
Mastoid effusion	Ear and labyrinth disorders	1	0.00 %
Maternal drugs affecting foetus	Injury, poisoning and procedural complications	1	0.00 %
Maternal exposure during delivery	Injury, poisoning and procedural complications	1	0.00 %
Maternal exposure via partner during pregnancy	Injury, poisoning and procedural complications	1	0.00 %
Mean cell haemoglobin concentration	Investigations	1	0.00 %
Measles antibody positive	Investigations	1	0.00 %
Mechanic's hand	Skin and subcutaneous tissue disorders	1	0.00 %
Mechanical ventilation complication	Injury, poisoning and procedural complications	1	0.00 %
Mediastinal cyst	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Mediastinal effusion	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Mediastinal haematoma	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Medical device site cyst	General disorders and administration site conditions	1	0.00 %
Medical device site erosion	General disorders and administration site conditions	1	0.00 %
Medical device site granuloma	General disorders and administration site conditions	1	0.00 %
Medical device site inflammation	General disorders and administration site conditions	1	0.00 %
Medical device site joint pain	General disorders and administration site conditions	1	0.00 %
Medical device site lymphadenopathy	General disorders and administration site conditions	1	0.00 %
Medical device site oedema	General disorders and administration site conditions	1	0.00 %
Medical device site pain	General disorders and administration site conditions	1	0.00 %
Medical device site paraesthesia	General disorders and administration site conditions	1	0.00 %
Medical device site pruritus	General disorders and administration site conditions	1	0.00 %
Medical device site recall reaction	General disorders and administration site conditions	1	0.00 %
Medication dilution	Surgical and medical procedures	1	0.00 %
Medulloblastoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Megakaryocytes	Investigations	1	0.00 %
Megakaryocytes abnormal	Investigations	1	0.00 %
Meibomian gland discharge	Eye disorders	1	0.00 %
MELAS syndrome	Congenital, familial and genetic disorders	1	0.00 %
Meningeal thickening	Nervous system disorders	1	0.00 %
Meningitis meningococcal	Infections and infestations	1	0.00 %
Meningitis neonatal	Infections and infestations	1	0.00 %
Meningitis staphylococcal	Infections and infestations	1	0.00 %
Meningocele	Congenital, familial and genetic disorders	1	0.00 %
Meningococcal bacteraemia	Infections and infestations	1	0.00 %
Meningomyelocele	Congenital, familial and genetic disorders	1	0.00 %
Meniscal degeneration	Musculoskeletal and connective tissue disorders	1	0.00 %
Menopausal depression	Psychiatric disorders	1	0.00 %
Mesenteric abscess	Infections and infestations	1	0.00 %
Mesenteric haematoma	Gastrointestinal disorders	1	0.00 %
Mesenteric vascular insufficiency	Gastrointestinal disorders	1	0.00 %
Mesenteric venous occlusion	Gastrointestinal disorders	1	0.00 %
Metabolic myopathy	Congenital, familial and genetic disorders	1	0.00 %
Metapneumovirus infection	Infections and infestations	1	0.00 %
Metastases to abdominal cavity	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Metastases to adrenals	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Metastases to breast	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Metastases to heart	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Metastases to neck	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Metastases to pituitary gland	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Metastases to skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Methaemoglobinaemia	Blood and lymphatic system disorders	1	0.00 %
Microcephaly	Congenital, familial and genetic disorders	1	0.00 %
Micrognathia	Congenital, familial and genetic disorders	1	0.00 %
Microphthalmos	Congenital, familial and genetic disorders	1	0.00 %
Microsporum infection	Infections and infestations	1	0.00 %
Mini mental status examination abnormal	Investigations	1	0.00 %
Misleading laboratory test result	Investigations	1	0.00 %
Mitochondrial encephalomyopathy	Congenital, familial and genetic disorders	1	0.00 %
Mitochondrial myopathy acquired	Musculoskeletal and connective tissue disorders	1	0.00 %
Mitral valve replacement	Surgical and medical procedures	1	0.00 %
Moebius II syndrome	Congenital, familial and genetic disorders	1	0.00 %
Molar abortion	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Monoclonal immunoglobulin increased	Investigations	1	0.00 %
Moraxella infection	Infections and infestations	1	0.00 %
Morbihan disease	Skin and subcutaneous tissue disorders	1	0.00 %
Morvan syndrome	Nervous system disorders	1	0.00 %
Mucocutaneous rash	Skin and subcutaneous tissue disorders	1	0.00 %
Mucocutaneous ulceration	Skin and subcutaneous tissue disorders	1	0.00 %
Mucormycosis	Infections and infestations	1	0.00 %
Mucosal atrophy	General disorders and administration site conditions	1	0.00 %
Mucosal excoriation	Injury, poisoning and procedural complications	1	0.00 %
Mucosal exfoliation	General disorders and administration site conditions	1	0.00 %
Mucosal necrosis	General disorders and administration site conditions	1	0.00 %
Mucosal roughness	General disorders and administration site conditions	1	0.00 %
Multigravida	Social circumstances	1	0.00 %
Mumps antibody test positive	Investigations	1	0.00 %
Muscle enzyme	Investigations	1	0.00 %
Muscle neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Muscle tension dysphonia	Nervous system disorders	1	0.00 %
Musculoskeletal deformity	Musculoskeletal and connective tissue disorders	1	0.00 %
Mycobacterial infection	Infections and infestations	1	0.00 %
Mycobacterium avium complex infection	Infections and infestations	1	0.00 %
Mycotoxicosis	Infections and infestations	1	0.00 %
Myelocyte count decreased	Investigations	1	0.00 %
Myelolipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Myeloma cast nephropathy	Renal and urinary disorders	1	0.00 %
Myocardial calcification	Cardiac disorders	1	0.00 %
Myocardial necrosis marker	Investigations	1	0.00 %
Myocarditis bacterial	Infections and infestations	1	0.00 %
Myoclonic epilepsy and ragged-red fibres	Congenital, familial and genetic disorders	1	0.00 %
Myoglobinaemia	Musculoskeletal and connective tissue disorders	1	0.00 %
Myomectomy	Surgical and medical procedures	1	0.00 %
Myopathy toxic	Musculoskeletal and connective tissue disorders	1	0.00 %
Myopic chorioretinal degeneration	Eye disorders	1	0.00 %
Myositis-like syndrome	Musculoskeletal and connective tissue disorders	1	0.00 %
Myotonic dystrophy	Congenital, familial and genetic disorders	1	0.00 %
Myxoedema coma	Nervous system disorders	1	0.00 %
Myxoid cyst	Skin and subcutaneous tissue disorders	1	0.00 %
Myxoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
N-terminal prohormone brain natriuretic peptide	Investigations	1	0.00 %
N-terminal prohormone brain natriuretic peptide decreased	Investigations	1	0.00 %
Naevus haemorrhage	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Naevus lipomatous cutaneous superficialis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Nail aplasia	Congenital, familial and genetic disorders	1	0.00 %
Nail cuticle fissure	Skin and subcutaneous tissue disorders	1	0.00 %
Nail fold inflammation	Skin and subcutaneous tissue disorders	1	0.00 %
Nail hypertrophy	Skin and subcutaneous tissue disorders	1	0.00 %
Nail necrosis	Skin and subcutaneous tissue disorders	1	0.00 %
Nail pitting	Skin and subcutaneous tissue disorders	1	0.00 %
Nasal cavity cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Nasal cavity mass	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal cyst	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal mucosa atrophy	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal mucosa telangiectasia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal mucosal discolouration	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal mucosal hypertrophy	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal necrosis	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasal septal operation	Surgical and medical procedures	1	0.00 %
Nasal turbinete abnormality	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Nasopharyngeal surgery	Surgical and medical procedures	1	0.00 %
Natural killer cell activity decreased	Investigations	1	0.00 %
Natural killer cell count decreased	Investigations	1	0.00 %
Natural killer cell count increased	Investigations	1	0.00 %
Natural killer T cell count decreased	Investigations	1	0.00 %
Neck crushing	Injury, poisoning and procedural complications	1	0.00 %
Neck lift	Surgical and medical procedures	1	0.00 %
Neck surgery	Surgical and medical procedures	1	0.00 %
Necrobiosis	General disorders and administration site conditions	1	0.00 %
Necrobiosis lipoidica diabetorum	Skin and subcutaneous tissue disorders	1	0.00 %
Necrolytic migratory erythema	Skin and subcutaneous tissue disorders	1	0.00 %
Necrosis ischaemic	Vascular disorders	1	0.00 %
Necrotic angiodermatitis	Skin and subcutaneous tissue disorders	1	0.00 %
Necrotising enterocolitis neonatal	Gastrointestinal disorders	1	0.00 %
Necrotising scleritis	Eye disorders	1	0.00 %
Necrotising soft tissue infection	Infections and infestations	1	0.00 %
Necrotising ulcerative periodontitis	Infections and infestations	1	0.00 %
Nematodiasis	Infections and infestations	1	0.00 %
Neonatal alloimmune thrombocytopenia	Congenital, familial and genetic disorders	1	0.00 %
Neonatal aspiration	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Neonatal deafness	Ear and labyrinth disorders	1	0.00 %
Neonatal dyspnoea	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Neonatal epileptic seizure	Nervous system disorders	1	0.00 %
Neonatal haemochromatosis	Congenital, familial and genetic disorders	1	0.00 %
Neonatal hepatomegaly	Hepatobiliary disorders	1	0.00 %
Neonatal hypocalcaemia	Metabolism and nutrition disorders	1	0.00 %
Neonatal hyponatraemia	Metabolism and nutrition disorders	1	0.00 %
Neonatal hypotension	Vascular disorders	1	0.00 %
Neonatal hypoxia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Neonatal intestinal obstruction	Gastrointestinal disorders	1	0.00 %
Neonatal multi-organ failure	General disorders and administration site conditions	1	0.00 %
Neonatal pneumonia	Infections and infestations	1	0.00 %
Neonatal respiratory acidosis	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Neonatal respiratory failure	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Neoplasm of orbit	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Neoplasm of thymus	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Neovaginal infection	Infections and infestations	1	0.00 %
Neovaginal pain	Injury, poisoning and procedural complications	1	0.00 %
Nephrectasia	Renal and urinary disorders	1	0.00 %
Nephritis allergic	Renal and urinary disorders	1	0.00 %
Nephritis bacterial	Infections and infestations	1	0.00 %
Nephroangiosclerosis	Renal and urinary disorders	1	0.00 %
Nephroblastoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Nephrocalcinosis	Renal and urinary disorders	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Nephrogenic diabetes insipidus	Renal and urinary disorders	1	0.00 %
Nerve conduction studies	Investigations	1	0.00 %
Nerve root injury lumbar	Injury, poisoning and procedural complications	1	0.00 %
Nerve root injury thoracic	Injury, poisoning and procedural complications	1	0.00 %
Neurilemmoma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Neuroendocrine carcinoma metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Neuroendocrine carcinoma of the skin	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Neuroendocrine tumour of the lung metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Neuroleptic-induced deficit syndrome	Psychiatric disorders	1	0.00 %
Neurological procedural complication	Injury, poisoning and procedural complications	1	0.00 %
Neurolysis	Surgical and medical procedures	1	0.00 %
Neuromyotonia	Nervous system disorders	1	0.00 %
Neuropsychiatric lupus	Nervous system disorders	1	0.00 %
Neuropsychiatric symptoms	Psychiatric disorders	1	0.00 %
Neuropsychiatric syndrome	Psychiatric disorders	1	0.00 %
Neurotransmitter level altered	Investigations	1	0.00 %
Neurovascular conflict	Nervous system disorders	1	0.00 %
Neutropenia neonatal	Blood and lymphatic system disorders	1	0.00 %
Neutrophil gelatinase-associated lipocalin increased	Investigations	1	0.00 %
Neutrophil morphology abnormal	Investigations	1	0.00 %
Neutrophil/lymphocyte ratio decreased	Investigations	1	0.00 %
Neutrophil/lymphocyte ratio increased	Investigations	1	0.00 %
NIH stroke scale abnormal	Investigations	1	0.00 %
NIH stroke scale score increased	Investigations	1	0.00 %
Nipple resection	Surgical and medical procedures	1	0.00 %
Nocturnal fear	Psychiatric disorders	1	0.00 %
Nodular fasciitis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Nodular lymphocyte predominant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Hodgkin lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Nodular melanoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Non-cardiogenic pulmonary oedema	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Non-small cell lung cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Noninfective chorioretinitis	Eye disorders	1	0.00 %
Noninfective epididymitis	Reproductive system and breast disorders	1	0.00 %
Norovirus test positive	Investigations	1	0.00 %
Nucleated red cells	Blood and lymphatic system disorders	1	0.00 %
Nutritional assessment	Investigations	1	0.00 %
NYHA classification	Investigations	1	0.00 %
Obliterative bronchiolitis	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Obsessive rumination	Psychiatric disorders	1	0.00 %
Obstructed labour	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Occult blood	Investigations	1	0.00 %
Occupational exposure to sunlight	Injury, poisoning and procedural complications	1	0.00 %
Occupational problem environmental	Social circumstances	1	0.00 %
Ocular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Oculocephalogyric reflex absent	Nervous system disorders	1	0.00 %
Odontogenic cyst	Congenital, familial and genetic disorders	1	0.00 %
Oedema due to hepatic disease	General disorders and administration site conditions	1	0.00 %
Oesophageal dilatation	Gastrointestinal disorders	1	0.00 %
Oesophageal infection	Infections and infestations	1	0.00 %
Oesophageal mass	Gastrointestinal disorders	1	0.00 %
Oesophageal motility disorder	Gastrointestinal disorders	1	0.00 %
Oesophageal mucosal blister	Gastrointestinal disorders	1	0.00 %
Oesophageal squamous cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Oesophagectomy	Surgical and medical procedures	1	0.00 %
Oesophagitis chemical	Injury, poisoning and procedural complications	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Oesophagogastroscopy normal	Investigations	1	0.00 %
Oestradiol abnormal	Investigations	1	0.00 %
Oestradiol decreased	Investigations	1	0.00 %
Oestrogen replacement therapy	Surgical and medical procedures	1	0.00 %
Oligoasthenoteratozoospermia	Reproductive system and breast disorders	1	0.00 %
Oligodendrogloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Omental haemorrhage	Gastrointestinal disorders	1	0.00 %
Oncocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ophthalmia neonatorum	Infections and infestations	1	0.00 %
Ophthalmic artery aneurysm	Eye disorders	1	0.00 %
Ophthalmological examination	Investigations	1	0.00 %
Opiates	Investigations	1	0.00 %
Opiates positive	Investigations	1	0.00 %
Oppositional defiant disorder	Psychiatric disorders	1	0.00 %
Optic discs blurred	Eye disorders	1	0.00 %
Optic glioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Optic nerve compression	Eye disorders	1	0.00 %
Optic nerve sheath haemorrhage	Eye disorders	1	0.00 %
Oral bacterial infection	Infections and infestations	1	0.00 %
Oral cavity fistula	Gastrointestinal disorders	1	0.00 %
Oral haemangioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Oral mucosal hypertrophy	Gastrointestinal disorders	1	0.00 %
Oral neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Oral papilloma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Orbital infection	Infections and infestations	1	0.00 %
Orchidectomy	Surgical and medical procedures	1	0.00 %
Orf	Infections and infestations	1	0.00 %
Oropharyngeal cobble stone mucosa	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Oropharyngeal neoplasm benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Oropharyngitis fungal	Infections and infestations	1	0.00 %
Orthodontic procedure	Surgical and medical procedures	1	0.00 %
Orthosis user	Social circumstances	1	0.00 %
Orthostatic heart rate response increased	Investigations	1	0.00 %
Osmolar gap increased	Investigations	1	0.00 %
Osmotic demyelination syndrome	Nervous system disorders	1	0.00 %
Osteitis condensans	Musculoskeletal and connective tissue disorders	1	0.00 %
Osteo-meningeal breaches	Musculoskeletal and connective tissue disorders	1	0.00 %
Osteogenesis imperfecta	Congenital, familial and genetic disorders	1	0.00 %
Osteoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Osteomyelitis bacterial	Infections and infestations	1	0.00 %
Osteomyelitis chronic	Infections and infestations	1	0.00 %
Osteoprotegerin ligand decreased	Investigations	1	0.00 %
Otitis externa bacterial	Infections and infestations	1	0.00 %
Otitis media bacterial	Infections and infestations	1	0.00 %
Ovarian bacterial infection	Infections and infestations	1	0.00 %
Ovarian cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ovarian cancer stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ovarian cancer stage IV	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ovarian epithelial cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ovarian germ cell cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Ovarian granulosa cell tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Ovarian haematoma	Reproductive system and breast disorders	1	0.00 %
Ovarian hyperfunction	Reproductive system and breast disorders	1	0.00 %
Ovarian hyperstimulation syndrome	Reproductive system and breast disorders	1	0.00 %
Ovarian operation	Surgical and medical procedures	1	0.00 %
Overfeeding of infant	Metabolism and nutrition disorders	1	0.00 %
Oxygen saturation normal	Investigations	1	0.00 %
Pacemaker syndrome	General disorders and administration site conditions	1	0.00 %
Packed red blood cell transfusion	Surgical and medical procedures	1	0.00 %
Paget's disease of nipple	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Paget's disease of the vulva	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Palmar fasciitis	Musculoskeletal and connective tissue disorders	1	0.00 %
Pancoast's syndrome	Nervous system disorders	1	0.00 %
Pancreas divisum	Congenital, familial and genetic disorders	1	0.00 %
Pancreatic abscess	Infections and infestations	1	0.00 %
Pancreatic enzymes decreased	Investigations	1	0.00 %
Pancreatic haemorrhage	Gastrointestinal disorders	1	0.00 %
Pancreatic infarction	Gastrointestinal disorders	1	0.00 %
Pancreatic injury	Injury, poisoning and procedural complications	1	0.00 %
Pancreatic operation	Surgical and medical procedures	1	0.00 %
Pancreatitis haemorrhagic	Gastrointestinal disorders	1	0.00 %
Pancreatogenous diabetes	Metabolism and nutrition disorders	1	0.00 %
PaO2/FiO2 ratio decreased	Investigations	1	0.00 %
Papilla of Vater sclerosis	Gastrointestinal disorders	1	0.00 %
Papillary muscle disorder	Cardiac disorders	1	0.00 %
Papillary muscle rupture	Cardiac disorders	1	0.00 %
Paracentesis	Investigations	1	0.00 %
Paradoxical pressor response	Vascular disorders	1	0.00 %
Paradoxical psoriasis	Skin and subcutaneous tissue disorders	1	0.00 %
Paraganglion neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Parainfluenzae viral laryngotracheobronchitis	Infections and infestations	1	0.00 %
Paralogism	Psychiatric disorders	1	0.00 %
Paralytic disability	Social circumstances	1	0.00 %
Paranasal sinus abscess	Infections and infestations	1	0.00 %
Paranasal sinus mucosal hypertrophy	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Paraneoplastic dermatomyositis	Skin and subcutaneous tissue disorders	1	0.00 %
Paraneoplastic encephalomyelitis	Nervous system disorders	1	0.00 %
Paraneoplastic thrombosis	Vascular disorders	1	0.00 %
Paranoid personality disorder	Psychiatric disorders	1	0.00 %
Paraproteinaemia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Parasitic test positive	Investigations	1	0.00 %
Parasympathetic nerve injury	Injury, poisoning and procedural complications	1	0.00 %
Parathyroid disorder	Endocrine disorders	1	0.00 %
Parathyroid tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Parathyroidectomy	Surgical and medical procedures	1	0.00 %
Parenteral nutrition	Surgical and medical procedures	1	0.00 %
Paresis anal sphincter	Gastrointestinal disorders	1	0.00 %
Parkes-Weber syndrome	Congenital, familial and genetic disorders	1	0.00 %
Parkinsonian crisis	Nervous system disorders	1	0.00 %
Parotid duct obstruction	Gastrointestinal disorders	1	0.00 %
Parotid lipomatosis	Gastrointestinal disorders	1	0.00 %
Paroxysmal autonomic instability with dystonia	Injury, poisoning and procedural complications	1	0.00 %
Paroxysmal perceptual alteration	Psychiatric disorders	1	0.00 %
Partial lipodystrophy	Skin and subcutaneous tissue disorders	1	0.00 %
Paternal exposure timing unspecified	Injury, poisoning and procedural complications	1	0.00 %
PCO2 abnormal	Investigations	1	0.00 %
Peak expiratory flow rate	Investigations	1	0.00 %
Pedal pulse abnormal	Investigations	1	0.00 %
Peliosis hepatitis	Hepatobiliary disorders	1	0.00 %
Pelvic abscess	Infections and infestations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Pelvic adhesions	Reproductive system and breast disorders	1	0.00 %
Pelvic floor stimulation	Surgical and medical procedures	1	0.00 %
Penile abscess	Infections and infestations	1	0.00 %
Penile curvature	Reproductive system and breast disorders	1	0.00 %
Penile erosion	Reproductive system and breast disorders	1	0.00 %
Penile wart	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Penoscrotal fusion	Congenital, familial and genetic disorders	1	0.00 %
Peptostreptococcus infection	Infections and infestations	1	0.00 %
Perforated ulcer	General disorders and administration site conditions	1	0.00 %
Performance fear	Psychiatric disorders	1	0.00 %
Perfusion brain scan abnormal	Investigations	1	0.00 %
Periarthritis calcarea	Metabolism and nutrition disorders	1	0.00 %
Periarticular disorder	Musculoskeletal and connective tissue disorders	1	0.00 %
Pericardial lipoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Pericardial mesothelioma malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Pericarditis adhesive	Cardiac disorders	1	0.00 %
Pericarditis lupus	Cardiac disorders	1	0.00 %
Pericarditis rheumatic	Cardiac disorders	1	0.00 %
Pericarditis tuberculous	Infections and infestations	1	0.00 %
Pericarditis uraemic	Cardiac disorders	1	0.00 %
Perihepatitis	Infections and infestations	1	0.00 %
Perinatal brain damage	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Perineal cellulitis	Infections and infestations	1	0.00 %
Perineal erythema	Reproductive system and breast disorders	1	0.00 %
Perinephric oedema	Renal and urinary disorders	1	0.00 %
Periodic limb movement disorder	Nervous system disorders	1	0.00 %
Periorbital abscess	Infections and infestations	1	0.00 %
Periorbital fat herniation	Eye disorders	1	0.00 %
Peripancreatic fluid collection	Injury, poisoning and procedural complications	1	0.00 %
Peripheral artery haematoma	Vascular disorders	1	0.00 %
Peripheral artery surgery	Surgical and medical procedures	1	0.00 %
Peripheral nerve neurostimulation	Surgical and medical procedures	1	0.00 %
Peripheral vein occlusion	Vascular disorders	1	0.00 %
Periprosthetic osteolysis	Injury, poisoning and procedural complications	1	0.00 %
Perirectal abscess	Infections and infestations	1	0.00 %
Peritoneal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Peritoneal perforation	Gastrointestinal disorders	1	0.00 %
Peritonsillitis	Infections and infestations	1	0.00 %
Periumbilical abscess	Infections and infestations	1	0.00 %
Persistent corneal epithelial defect	Injury, poisoning and procedural complications	1	0.00 %
Persistent foetal circulation	Congenital, familial and genetic disorders	1	0.00 %
Personality change due to a general medical condition	Psychiatric disorders	1	0.00 %
Petroleum distillate poisoning	Injury, poisoning and procedural complications	1	0.00 %
Pfeiffer syndrome	Congenital, familial and genetic disorders	1	0.00 %
pH body fluid	Investigations	1	0.00 %
pH body fluid increased	Investigations	1	0.00 %
pH urine abnormal	Investigations	1	0.00 %
Phantom vibration syndrome	Psychiatric disorders	1	0.00 %
Pharyngeal dyskinesia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pharyngeal erosion	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pharyngeal haematoma	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pharyngeal leukoplakia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pharyngo-oesophageal diverticulum	Gastrointestinal disorders	1	0.00 %
Phelan-McDermid syndrome	Congenital, familial and genetic disorders	1	0.00 %
Philadelphia chromosome positive	Investigations	1	0.00 %
Phlebitis infective	Infections and infestations	1	0.00 %
Phobia of driving	Psychiatric disorders	1	0.00 %
Phonasthenia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Phrenic nerve injury	Injury, poisoning and procedural complications	1	0.00 %
Phrenic nerve irritation	Nervous system disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Phyllodes tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Physical fitness training	Surgical and medical procedures	1	0.00 %
Pica	Psychiatric disorders	1	0.00 %
Pituitary infarction	Endocrine disorders	1	0.00 %
Pituitary scan abnormal	Investigations	1	0.00 %
Pituitary-dependent Cushing's syndrome	Endocrine disorders	1	0.00 %
Placenta growth factor	Investigations	1	0.00 %
Placental calcification	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Placental necrosis	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Plague	Infections and infestations	1	0.00 %
Plasma cell disorder	Blood and lymphatic system disorders	1	0.00 %
Plasma cells increased	Investigations	1	0.00 %
Platelet count normal	Investigations	1	0.00 %
Platelet destruction increased	Blood and lymphatic system disorders	1	0.00 %
Platelet factor 4 decreased	Investigations	1	0.00 %
Platelet production decreased	Blood and lymphatic system disorders	1	0.00 %
Platelet transfusion	Surgical and medical procedures	1	0.00 %
Plateletcrit abnormal	Investigations	1	0.00 %
Platymbasia	Congenital, familial and genetic disorders	1	0.00 %
Pleomorphic malignant fibrous histiocytoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Plethoric face	Vascular disorders	1	0.00 %
Pleural adhesion	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pleural decortication	Surgical and medical procedures	1	0.00 %
Pleural mass	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pleural mesothelioma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Pleural mesothelioma malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Pleurisy bacterial	Infections and infestations	1	0.00 %
Pleurothotonus	Nervous system disorders	1	0.00 %
Pneumobilia	Hepatobiliary disorders	1	0.00 %
Pneumococcal bacteraemia	Infections and infestations	1	0.00 %
Pneumonia cytomegaloviral	Infections and infestations	1	0.00 %
Pneumonia escherichia	Infections and infestations	1	0.00 %
Pneumonia moraxella	Infections and infestations	1	0.00 %
Pneumonia proteus	Infections and infestations	1	0.00 %
Pneumonia respiratory syncytial viral	Infections and infestations	1	0.00 %
Pneumonitis chemical	Injury, poisoning and procedural complications	1	0.00 %
Pneumopericardium	Cardiac disorders	1	0.00 %
PO2 abnormal	Investigations	1	0.00 %
Pocket erosion	Injury, poisoning and procedural complications	1	0.00 %
Poikiloderma	Skin and subcutaneous tissue disorders	1	0.00 %
Poliomyelitis	Infections and infestations	1	0.00 %
Polycystic liver disease	Congenital, familial and genetic disorders	1	0.00 %
Polycythaemia neonatorum	Blood and lymphatic system disorders	1	0.00 %
Polyglandular autoimmune syndrome type I	Endocrine disorders	1	0.00 %
Polyglandular autoimmune syndrome type II	Endocrine disorders	1	0.00 %
Polymicrogyria	Congenital, familial and genetic disorders	1	0.00 %
Polymorphic eruption of pregnancy	Skin and subcutaneous tissue disorders	1	0.00 %
Polyneuropathy in malignant disease	Nervous system disorders	1	0.00 %
Polyomavirus viraemia	Infections and infestations	1	0.00 %
Poor dental condition	Gastrointestinal disorders	1	0.00 %
Poor quality device used	Injury, poisoning and procedural complications	1	0.00 %
Poor sucking reflex	Nervous system disorders	1	0.00 %
Poorly differentiated thyroid carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Porencephaly	Congenital, familial and genetic disorders	1	0.00 %
Poriomania	Psychiatric disorders	1	0.00 %
Porokeratosis	Congenital, familial and genetic disorders	1	0.00 %
Porphyria non-acute	Congenital, familial and genetic disorders	1	0.00 %
Portal vein dilatation	Hepatobiliary disorders	1	0.00 %
Positive airway pressure therapy	Surgical and medical procedures	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Positive cardiac inotropic effect	Cardiac disorders	1	0.00 %
Post laminectomy syndrome	Injury, poisoning and procedural complications	1	0.00 %
Post polio syndrome	Nervous system disorders	1	0.00 %
Post procedural complication circulatory	Injury, poisoning and procedural complications	1	0.00 %
Post procedural constipation	Injury, poisoning and procedural complications	1	0.00 %
Post procedural contusion	Injury, poisoning and procedural complications	1	0.00 %
Post procedural discomfort	Injury, poisoning and procedural complications	1	0.00 %
Post procedural erythema	Injury, poisoning and procedural complications	1	0.00 %
Post procedural haematuria	Injury, poisoning and procedural complications	1	0.00 %
Post procedural hypothyroidism	Injury, poisoning and procedural complications	1	0.00 %
Post procedural pruritus	Injury, poisoning and procedural complications	1	0.00 %
Post procedural pulmonary embolism	Injury, poisoning and procedural complications	1	0.00 %
Post procedural stroke	Injury, poisoning and procedural complications	1	0.00 %
Post streptococcal glomerulonephritis	Renal and urinary disorders	1	0.00 %
Post stroke depression	Psychiatric disorders	1	0.00 %
Post stroke seizure	Nervous system disorders	1	0.00 %
Post treatment Lyme disease syndrome	Infections and infestations	1	0.00 %
Post-anaphylaxis mast cell anergy	Blood and lymphatic system disorders	1	0.00 %
Post-anoxic myoclonus	Nervous system disorders	1	0.00 %
Post-traumatic neuralgia	Nervous system disorders	1	0.00 %
Posterior capsule opacification	Eye disorders	1	0.00 %
Posterior capsule rupture	Injury, poisoning and procedural complications	1	0.00 %
Posterior fossa decompression	Surgical and medical procedures	1	0.00 %
Posthaemorrhagic hydrocephalus	Nervous system disorders	1	0.00 %
Postictal headache	Nervous system disorders	1	0.00 %
Postinfarction angina	Cardiac disorders	1	0.00 %
Postmastectomy lymphoedema syndrome	Injury, poisoning and procedural complications	1	0.00 %
Postoperative abscess	Infections and infestations	1	0.00 %
Postoperative analgesia	Surgical and medical procedures	1	0.00 %
Postoperative ileus	Injury, poisoning and procedural complications	1	0.00 %
Postpartum stress disorder	Psychiatric disorders	1	0.00 %
Postrenal failure	Renal and urinary disorders	1	0.00 %
Postresuscitation encephalopathy	Nervous system disorders	1	0.00 %
Potter's syndrome	Congenital, familial and genetic disorders	1	0.00 %
Poverty of thought content	Psychiatric disorders	1	0.00 %
Prealbumin decreased	Investigations	1	0.00 %
Precerebral artery occlusion	Nervous system disorders	1	0.00 %
Precerebral artery thrombosis	Nervous system disorders	1	0.00 %
Pregnancy in habitual aborter	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Pregnancy of unknown location	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Pregnancy test urine negative	Investigations	1	0.00 %
Premature follicular ripening	Reproductive system and breast disorders	1	0.00 %
Prepuce dorsal slit	Surgical and medical procedures	1	0.00 %
Prescribed overdose	Injury, poisoning and procedural complications	1	0.00 %
Primary amyloidosis	Immune system disorders	1	0.00 %
Primary gastrointestinal follicular lymphoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Primary myelofibrosis	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Primary progressive multiple sclerosis	Nervous system disorders	1	0.00 %
Probiotic therapy	Surgical and medical procedures	1	0.00 %
Procedural pneumothorax	Injury, poisoning and procedural complications	1	0.00 %
Procrastination	Psychiatric disorders	1	0.00 %
Prodromal Alzheimer's disease	Nervous system disorders	1	0.00 %
Product adhesion issue	Product issues	1	0.00 %
Product administered by wrong person	Injury, poisoning and procedural complications	1	0.00 %
Product contamination microbial	Product issues	1	0.00 %
Product counterfeit	Product issues	1	0.00 %
Product delivery mechanism issue	Product issues	1	0.00 %
Product design issue	Product issues	1	0.00 %
Product dispensing issue	Injury, poisoning and procedural complications	1	0.00 %
Product dosage form confusion	Injury, poisoning and procedural complications	1	0.00 %
Product name confusion	Injury, poisoning and procedural complications	1	0.00 %
Product origin unknown	Product issues	1	0.00 %
Product physical consistency issue	Product issues	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Product substitution	Surgical and medical procedures	1	0.00 %
Product substitution error	Injury, poisoning and procedural complications	1	0.00 %
Progressive facial hemiatrophy	Skin and subcutaneous tissue disorders	1	0.00 %
Promyelocyte count increased	Investigations	1	0.00 %
Pronator teres syndrome	Nervous system disorders	1	0.00 %
Propofol infusion syndrome	Metabolism and nutrition disorders	1	0.00 %
Prostate cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Prostate examination abnormal	Investigations	1	0.00 %
Prostate tenderness	Reproductive system and breast disorders	1	0.00 %
Prostatic abscess	Infections and infestations	1	0.00 %
Prostatic atrophy	Reproductive system and breast disorders	1	0.00 %
Prostatic calcification	Reproductive system and breast disorders	1	0.00 %
Prostatic haemorrhage	Reproductive system and breast disorders	1	0.00 %
Prostatic obstruction	Reproductive system and breast disorders	1	0.00 %
Prostatism	Reproductive system and breast disorders	1	0.00 %
Prosthetic vessel implantation	Surgical and medical procedures	1	0.00 %
Protein albumin ratio	Investigations	1	0.00 %
Protein S abnormal	Investigations	1	0.00 %
Protein S increased	Investigations	1	0.00 %
Protein urine absent	Investigations	1	0.00 %
Protein-losing gastroenteropathy	Gastrointestinal disorders	1	0.00 %
Prothrombin consumption time shortened	Investigations	1	0.00 %
Protrusion tongue	Gastrointestinal disorders	1	0.00 %
Pseudo-Bartter syndrome	Metabolism and nutrition disorders	1	0.00 %
Pseudoangina	General disorders and administration site conditions	1	0.00 %
Pseudobulbar palsy	Nervous system disorders	1	0.00 %
Pseudohernia	General disorders and administration site conditions	1	0.00 %
Pseudomenstruation neonatal	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Pseudopapilloedema	Eye disorders	1	0.00 %
Pseudoparalysis	Nervous system disorders	1	0.00 %
Pseudophakic bullous keratopathy	Injury, poisoning and procedural complications	1	0.00 %
Pseudoporphyria	Skin and subcutaneous tissue disorders	1	0.00 %
Pseudoradicicular syndrome	Nervous system disorders	1	0.00 %
Pseudothrombophlebitis	Musculoskeletal and connective tissue disorders	1	0.00 %
Psittacosis	Infections and infestations	1	0.00 %
Psychogenic tremor	Psychiatric disorders	1	0.00 %
Psychogenic visual disorder	Psychiatric disorders	1	0.00 %
Psychomotor disadaptation syndrome	Nervous system disorders	1	0.00 %
PTEN gene mutation	Congenital, familial and genetic disorders	1	0.00 %
Puberty	Social circumstances	1	0.00 %
Pulmonary air leakage	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pulmonary arterial pressure abnormal	Investigations	1	0.00 %
Pulmonary arterial wedge pressure decreased	Investigations	1	0.00 %
Pulmonary arterial wedge pressure increased	Investigations	1	0.00 %
Pulmonary artery stenosis congenital	Congenital, familial and genetic disorders	1	0.00 %
Pulmonary eosinophilia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pulmonary function test	Investigations	1	0.00 %
Pulmonary imaging procedure abnormal	Investigations	1	0.00 %
Pulmonary malformation	Congenital, familial and genetic disorders	1	0.00 %
Pulmonary physical examination abnormal	Investigations	1	0.00 %
Pulmonary pneumatocele	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Pulmonary sequestration	Congenital, familial and genetic disorders	1	0.00 %
Pulmonary valve thickening	Cardiac disorders	1	0.00 %
Pulmonary vascular disorder	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Puncture site discharge	General disorders and administration site conditions	1	0.00 %
Puncture site infection	Infections and infestations	1	0.00 %
Pupil dilation procedure	Investigations	1	0.00 %
Purgung	Psychiatric disorders	1	0.00 %
Purple glove syndrome	Musculoskeletal and connective tissue disorders	1	0.00 %
Purple urine bag syndrome	Infections and infestations	1	0.00 %
Purulent pericarditis	Infections and infestations	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Pus in stool	Investigations	1	0.00 %
Pyelonephritis fungal	Infections and infestations	1	0.00 %
Pylorospasm	Gastrointestinal disorders	1	0.00 %
Pyoderma streptococcal	Infections and infestations	1	0.00 %
Pyometra	Infections and infestations	1	0.00 %
Pyomyositis	Infections and infestations	1	0.00 %
Radial nerve compression	Nervous system disorders	1	0.00 %
Radiation interaction	General disorders and administration site conditions	1	0.00 %
Radiation mastitis	Injury, poisoning and procedural complications	1	0.00 %
Radiation proctitis	Injury, poisoning and procedural complications	1	0.00 %
Radiation skin injury	Injury, poisoning and procedural complications	1	0.00 %
Radical hysterectomy	Surgical and medical procedures	1	0.00 %
Radioisotope uptake increased	Investigations	1	0.00 %
Ranula	Gastrointestinal disorders	1	0.00 %
Raoultella ornithinolytica infection	Infections and infestations	1	0.00 %
Raymond-Cestan syndrome	Nervous system disorders	1	0.00 %
Re-opening of ductus arteriosus	Injury, poisoning and procedural complications	1	0.00 %
Reaction to azo-dyes	Immune system disorders	1	0.00 %
Reactive perforating collagenosis	Skin and subcutaneous tissue disorders	1	0.00 %
Rebound atopic dermatitis	Skin and subcutaneous tissue disorders	1	0.00 %
Rebound tachycardia	Cardiac disorders	1	0.00 %
Recession of chamber angle of eye	Eye disorders	1	0.00 %
Rectal cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Rectal injury	Injury, poisoning and procedural complications	1	0.00 %
Rectal lesion	Gastrointestinal disorders	1	0.00 %
Rectal perforation	Gastrointestinal disorders	1	0.00 %
Rectourethral fistula	Gastrointestinal disorders	1	0.00 %
Red blood cell anisocytes present	Investigations	1	0.00 %
Red blood cell nucleated morphology	Investigations	1	0.00 %
Red blood cell sedimentation rate	Investigations	1	0.00 %
Red breast syndrome	Reproductive system and breast disorders	1	0.00 %
Refractoriness to platelet transfusion	Injury, poisoning and procedural complications	1	0.00 %
Refractory cytopenia with unilineage dysplasia	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Refusal of vaccination	Social circumstances	1	0.00 %
Renal arteriosclerosis	Renal and urinary disorders	1	0.00 %
Renal artery dissection	Renal and urinary disorders	1	0.00 %
Renal artery occlusion	Renal and urinary disorders	1	0.00 %
Renal artery stent placement	Surgical and medical procedures	1	0.00 %
Renal dysplasia	Congenital, familial and genetic disorders	1	0.00 %
Renal failure neonatal	Renal and urinary disorders	1	0.00 %
Renal fusion anomaly	Congenital, familial and genetic disorders	1	0.00 %
Renal graft infection	Infections and infestations	1	0.00 %
Renal haematoma	Renal and urinary disorders	1	0.00 %
Renal tumour excision	Surgical and medical procedures	1	0.00 %
Renin	Investigations	1	0.00 %
Renin increased	Investigations	1	0.00 %
Renin-angiotensin system inhibition	General disorders and administration site conditions	1	0.00 %
Renovascular hypertension	Vascular disorders	1	0.00 %
Reperfusion injury	Vascular disorders	1	0.00 %
Reproductive tract anastomotic leak	Injury, poisoning and procedural complications	1	0.00 %
Respiratory depth increased	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Respiratory fremitus	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Respiratory fume inhalation disorder	Injury, poisoning and procedural complications	1	0.00 %
Respiratory moniliasis	Infections and infestations	1	0.00 %
Respiratory sinus arrhythmia magnitude	Investigations	1	0.00 %
Respiratory sinus arrhythmia magnitude abnormal	Investigations	1	0.00 %
Respiratory syncytial virus bronchitis	Infections and infestations	1	0.00 %
Respiratory tract chlamydial infection	Infections and infestations	1	0.00 %
Retained products of conception	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Reticular erythematous mucinosis	Skin and subcutaneous tissue disorders	1	0.00 %
Reticulocyte percentage increased	Investigations	1	0.00 %
Reticuloendothelial dysfunction	Blood and lymphatic system disorders	1	0.00 %
Retinal artery stenosis	Eye disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Retinal cryoablation	Surgical and medical procedures	1	0.00 %
Retinal depigmentation	Eye disorders	1	0.00 %
Retinal fibrosis	Eye disorders	1	0.00 %
Retinal vein varices	Eye disorders	1	0.00 %
Retinal vessel avulsion	Eye disorders	1	0.00 %
Retrognathia	Musculoskeletal and connective tissue disorders	1	0.00 %
Retroperitoneal abscess	Infections and infestations	1	0.00 %
Retroperitoneal effusion	Gastrointestinal disorders	1	0.00 %
Retroperitoneal mass	Gastrointestinal disorders	1	0.00 %
Retroperitoneal neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Rhabdoid tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Rhabdomyosarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Rhegmatogenous retinal detachment	Eye disorders	1	0.00 %
Rhesus antigen positive	Investigations	1	0.00 %
Rheumatoid bursitis	Musculoskeletal and connective tissue disorders	1	0.00 %
Rheumatoid vasculitis	Vascular disorders	1	0.00 %
Rhinitis atrophic	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Rhinotracheitis	Infections and infestations	1	0.00 %
Rhythm idioventricular	Cardiac disorders	1	0.00 %
Rib deformity	Musculoskeletal and connective tissue disorders	1	0.00 %
Richter's syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Rickettsiosis	Infections and infestations	1	0.00 %
Right atrial volume abnormal	Investigations	1	0.00 %
Right atrial volume decreased	Investigations	1	0.00 %
Right ventricular diastolic collapse	Cardiac disorders	1	0.00 %
Right ventricular ejection fraction decreased	Investigations	1	0.00 %
Rinne tuning fork test abnormal	Investigations	1	0.00 %
Rippling muscle disease	Congenital, familial and genetic disorders	1	0.00 %
Risk of future pregnancy miscarriage	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Rocky mountain spotted fever	Infections and infestations	1	0.00 %
Rosai-Dorfman syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Rotator cuff injury of hip	Musculoskeletal and connective tissue disorders	1	0.00 %
Rotator cuff repair	Surgical and medical procedures	1	0.00 %
Routine health maintenance	Surgical and medical procedures	1	0.00 %
Rubella antibody positive	Investigations	1	0.00 %
Rubella in pregnancy	Infections and infestations	1	0.00 %
Rubivirus test positive	Investigations	1	0.00 %
RUNX1 gene mutation	Congenital, familial and genetic disorders	1	0.00 %
Sacral radiculopathy	Nervous system disorders	1	0.00 %
Salivary gland cyst	Gastrointestinal disorders	1	0.00 %
Salt intoxication	Metabolism and nutrition disorders	1	0.00 %
Scan abdomen abnormal	Investigations	1	0.00 %
Scan gallium abnormal	Investigations	1	0.00 %
Scan myocardial perfusion abnormal	Investigations	1	0.00 %
Schellong test	Investigations	1	0.00 %
Schirmer's test abnormal	Investigations	1	0.00 %
Schistocytosis	Blood and lymphatic system disorders	1	0.00 %
Schizencephaly	Congenital, familial and genetic disorders	1	0.00 %
Schizoid personality disorder	Psychiatric disorders	1	0.00 %
School refusal	Psychiatric disorders	1	0.00 %
Scimitar syndrome	Congenital, familial and genetic disorders	1	0.00 %
Scleral pigmentation	Eye disorders	1	0.00 %
Scleroderma associated digital ulcer	Skin and subcutaneous tissue disorders	1	0.00 %
Scleroedema	Skin and subcutaneous tissue disorders	1	0.00 %
Sclerotherapy	Surgical and medical procedures	1	0.00 %
Scrotal abscess	Infections and infestations	1	0.00 %
Scrotal cellulitis	Infections and infestations	1	0.00 %
Scrotal haemorrhage	Reproductive system and breast disorders	1	0.00 %
Scrotal injury	Injury, poisoning and procedural complications	1	0.00 %
Scrotal irritation	Reproductive system and breast disorders	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Scrotal ulcer	Reproductive system and breast disorders	1	0.00 %
Scrotum erosion	Reproductive system and breast disorders	1	0.00 %
Sebaceous glands overactivity	Skin and subcutaneous tissue disorders	1	0.00 %
Second trimester pregnancy	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Secondary hyperthyroidism	Endocrine disorders	1	0.00 %
Secondary hypogonadism	Endocrine disorders	1	0.00 %
Selenium deficiency	Metabolism and nutrition disorders	1	0.00 %
Self-destructive behaviour	Psychiatric disorders	1	0.00 %
Self-induced vomiting	Psychiatric disorders	1	0.00 %
Semen discolouration	Reproductive system and breast disorders	1	0.00 %
Semen viscosity decreased	Investigations	1	0.00 %
Semen viscosity increased	Investigations	1	0.00 %
Semen volume abnormal	Investigations	1	0.00 %
Semenuria	Renal and urinary disorders	1	0.00 %
Seminal vesicular infection	Infections and infestations	1	0.00 %
Seminoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Sensory ganglionitis	Nervous system disorders	1	0.00 %
Sensory neuropathy hereditary	Congenital, familial and genetic disorders	1	0.00 %
Septal panniculitis	Skin and subcutaneous tissue disorders	1	0.00 %
Septic coagulopathy	Infections and infestations	1	0.00 %
Septic pulmonary embolism	Infections and infestations	1	0.00 %
Serology abnormal	Investigations	1	0.00 %
Serotonin deficiency	Nervous system disorders	1	0.00 %
Serum amyloid A protein increased	Investigations	1	0.00 %
Serum colour abnormal	Investigations	1	0.00 %
Serum ferritin	Investigations	1	0.00 %
Shagreen skin	Skin and subcutaneous tissue disorders	1	0.00 %
Shift to the right	Investigations	1	0.00 %
Short-chain acyl-coenzyme A dehydrogenase deficiency	Congenital, familial and genetic disorders	1	0.00 %
Shoulder dystocia	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Shunt blood flow excessive	Injury, poisoning and procedural complications	1	0.00 %
Shunt stenosis	Injury, poisoning and procedural complications	1	0.00 %
Sick building syndrome	General disorders and administration site conditions	1	0.00 %
Sigmoidoscopy abnormal	Investigations	1	0.00 %
Silicosis	Injury, poisoning and procedural complications	1	0.00 %
Single atrium	Congenital, familial and genetic disorders	1	0.00 %
Single functional kidney	Renal and urinary disorders	1	0.00 %
Sinobronchitis	Infections and infestations	1	0.00 %
Sinus tarsi syndrome	Musculoskeletal and connective tissue disorders	1	0.00 %
Sinusitis fungal	Infections and infestations	1	0.00 %
Sitophobia	Psychiatric disorders	1	0.00 %
Skin cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Skin cosmetic procedure	Surgical and medical procedures	1	0.00 %
Skin degenerative disorder	Skin and subcutaneous tissue disorders	1	0.00 %
Skin fibrosis	Skin and subcutaneous tissue disorders	1	0.00 %
Skin flap necrosis	Injury, poisoning and procedural complications	1	0.00 %
Skin hyperplasia	Skin and subcutaneous tissue disorders	1	0.00 %
Skin maceration	Skin and subcutaneous tissue disorders	1	0.00 %
Skin neoplasm excision	Surgical and medical procedures	1	0.00 %
Skin operation	Surgical and medical procedures	1	0.00 %
Skin scar contracture	Injury, poisoning and procedural complications	1	0.00 %
Skin squamous cell carcinoma metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Skin ulcer haemorrhage	Skin and subcutaneous tissue disorders	1	0.00 %
Sleep disorder therapy	Surgical and medical procedures	1	0.00 %
Sleep-related eating disorder	Psychiatric disorders	1	0.00 %
Slow vital capacity	Investigations	1	0.00 %
Small airways disease	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Small cell lung cancer metastatic	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Small intestinal stenosis	Gastrointestinal disorders	1	0.00 %
Small intestine carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Small intestine gangrene	Infections and infestations	1	0.00 %
Smallpox immunisation	Surgical and medical procedures	1	0.00 %
Sodium retention	Metabolism and nutrition disorders	1	0.00 %
Solid organ transplant rejection	Immune system disorders	1	0.00 %
Solitary fibrous tumour	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Soluble fibrin monomer complex increased	Investigations	1	0.00 %
Somatic hallucination	Psychiatric disorders	1	0.00 %
Somnolence neonatal	Nervous system disorders	1	0.00 %
Sperm analysis abnormal	Investigations	1	0.00 %
Sperm concentration increased	Investigations	1	0.00 %
Spermatic cord haemorrhage	Reproductive system and breast disorders	1	0.00 %
Spherocytic anaemia	Blood and lymphatic system disorders	1	0.00 %
Spinal cord herniation	Nervous system disorders	1	0.00 %
Spinal cord injury cauda equina	Injury, poisoning and procedural complications	1	0.00 %
Spinal cord injury cervical	Injury, poisoning and procedural complications	1	0.00 %
Spinal decompression	Surgical and medical procedures	1	0.00 %
Spinal epidural haemorrhage	Nervous system disorders	1	0.00 %
Spinal fusion acquired	Musculoskeletal and connective tissue disorders	1	0.00 %
Spinal meningioma benign	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Spinal muscular atrophy	Congenital, familial and genetic disorders	1	0.00 %
Spinal myelogram abnormal	Investigations	1	0.00 %
Spinal retrolisthesis	Musculoskeletal and connective tissue disorders	1	0.00 %
Spinal shock	Injury, poisoning and procedural complications	1	0.00 %
Spinal subdural haemorrhage	Nervous system disorders	1	0.00 %
Spinal synovial cyst	Musculoskeletal and connective tissue disorders	1	0.00 %
Spinal vessel congenital anomaly	Congenital, familial and genetic disorders	1	0.00 %
Spindle cell sarcoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Spleen atrophy	Blood and lymphatic system disorders	1	0.00 %
Spleen congestion	Blood and lymphatic system disorders	1	0.00 %
Splenic embolism	Blood and lymphatic system disorders	1	0.00 %
Splenic granuloma	Blood and lymphatic system disorders	1	0.00 %
Splenic haematoma	Blood and lymphatic system disorders	1	0.00 %
Splenic induration	Blood and lymphatic system disorders	1	0.00 %
Splenic necrosis	Blood and lymphatic system disorders	1	0.00 %
Spondylitic myelopathy	Nervous system disorders	1	0.00 %
Sports injury	Injury, poisoning and procedural complications	1	0.00 %
Sputum normal	Investigations	1	0.00 %
Squamous cell carcinoma of the oral cavity	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Squamous cell carcinoma of the tongue	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Staphyloma	Eye disorders	1	0.00 %
Stargardt's disease	Congenital, familial and genetic disorders	1	0.00 %
Stasis syndrome	Gastrointestinal disorders	1	0.00 %
Steatohepatitis	Hepatobiliary disorders	1	0.00 %
Stenocephaly	Musculoskeletal and connective tissue disorders	1	0.00 %
Stenotrophomonas bacteraemia	Infections and infestations	1	0.00 %
Stenotrophomonas test positive	Investigations	1	0.00 %
Sterilisation	Surgical and medical procedures	1	0.00 %
Sternal injury	Injury, poisoning and procedural complications	1	0.00 %
Steroid dependence	General disorders and administration site conditions	1	0.00 %
Stockholm syndrome	Psychiatric disorders	1	0.00 %
Stoma complication	Injury, poisoning and procedural complications	1	0.00 %
Stoma obstruction	Injury, poisoning and procedural complications	1	0.00 %
Stoma site erythema	Injury, poisoning and procedural complications	1	0.00 %
Stoma site extravasation	Injury, poisoning and procedural complications	1	0.00 %
Stoma site hypergranulation	Injury, poisoning and procedural complications	1	0.00 %
Stoma site inflammation	Injury, poisoning and procedural complications	1	0.00 %
Strangulated hernia	General disorders and administration site conditions	1	0.00 %
Streptococcal abscess	Infections and infestations	1	0.00 %
Streptococcal endocarditis	Infections and infestations	1	0.00 %
Strongyloides test positive	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Strongyloidiasis	Infections and infestations	1	0.00 %
Stump appendicitis	Infections and infestations	1	0.00 %
Sturge-Weber syndrome	Congenital, familial and genetic disorders	1	0.00 %
Subacute combined cord degeneration	Nervous system disorders	1	0.00 %
Subacute endocarditis	Infections and infestations	1	0.00 %
Subacute kidney injury	Renal and urinary disorders	1	0.00 %
Subacute sclerosing panencephalitis	Infections and infestations	1	0.00 %
Subcapsular hepatic haematoma	Hepatobiliary disorders	1	0.00 %
Subclavian artery aneurysm	Vascular disorders	1	0.00 %
Subclavian artery dissection	Vascular disorders	1	0.00 %
Subclavian artery embolism	Vascular disorders	1	0.00 %
Subclavian artery stenosis	Vascular disorders	1	0.00 %
Subclavian vein stenosis	Vascular disorders	1	0.00 %
Subdural abscess	Infections and infestations	1	0.00 %
Subendocardial haemorrhage	Cardiac disorders	1	0.00 %
Subperiosteal abscess	Infections and infestations	1	0.00 %
Substance dependence	Psychiatric disorders	1	0.00 %
Sudden unexplained death in epilepsy	General disorders and administration site conditions	1	0.00 %
Sunscreen sensitivity	Immune system disorders	1	0.00 %
Superficial siderosis of central nervous system	Nervous system disorders	1	0.00 %
Superinfection viral	Infections and infestations	1	0.00 %
Superior mesenteric artery syndrome	Gastrointestinal disorders	1	0.00 %
Superior semicircular canal dehiscence	Ear and labyrinth disorders	1	0.00 %
Superior vena cava occlusion	Vascular disorders	1	0.00 %
Supranuclear palsy	Nervous system disorders	1	0.00 %
Suspected suicide	Psychiatric disorders	1	0.00 %
Suture rupture	Injury, poisoning and procedural complications	1	0.00 %
Sweat gland infection	Infections and infestations	1	0.00 %
Sweat test	Investigations	1	0.00 %
Swollen joint count	Investigations	1	0.00 %
Swollen joint count increased	Investigations	1	0.00 %
Sydenham's chorea	Nervous system disorders	1	0.00 %
Symplepharon	Eye disorders	1	0.00 %
Sympathetic nerve injury	Injury, poisoning and procedural complications	1	0.00 %
Sympathetic ophthalmia	Eye disorders	1	0.00 %
Sympathomimetic effect	Nervous system disorders	1	0.00 %
Symptom masked	General disorders and administration site conditions	1	0.00 %
Synovial fluid analysis abnormal	Investigations	1	0.00 %
Syphilis genital	Infections and infestations	1	0.00 %
Systemic bacterial infection	Infections and infestations	1	0.00 %
Systemic leakage	General disorders and administration site conditions	1	0.00 %
Systemic lupus erythematosus disease activity index abnormal	Investigations	1	0.00 %
Systemic lupus erythematosus disease activity index decreased	Investigations	1	0.00 %
Systemic sclerosis pulmonary	Respiratory, thoracic and mediastinal disorders	1	0.00 %
T-cell lymphoma recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Taciturnity	Psychiatric disorders	1	0.00 %
Tanning	Social circumstances	1	0.00 %
Tear discolouration	Eye disorders	1	0.00 %
Telangiectasia congenital	Congenital, familial and genetic disorders	1	0.00 %
TEMPI syndrome	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Tendon laxity	Musculoskeletal and connective tissue disorders	1	0.00 %
Teratoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Terminal agitation	General disorders and administration site conditions	1	0.00 %
Testicular appendage torsion	Reproductive system and breast disorders	1	0.00 %
Testicular atrophy	Reproductive system and breast disorders	1	0.00 %
Testicular hypertrophy	Reproductive system and breast disorders	1	0.00 %
Testicular mass	Reproductive system and breast disorders	1	0.00 %
Testicular microlithiasis	Reproductive system and breast disorders	1	0.00 %
Testicular necrosis	Reproductive system and breast disorders	1	0.00 %
Testicular operation	Surgical and medical procedures	1	0.00 %

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Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Therapeutic embolisation	Surgical and medical procedures	1	0.00 %
Therapeutic hypothermia	Surgical and medical procedures	1	0.00 %
Therapeutic product effect variable	General disorders and administration site conditions	1	0.00 %
Therapeutic response delayed	General disorders and administration site conditions	1	0.00 %
Therapeutic response increased	General disorders and administration site conditions	1	0.00 %
Therapeutic skin care topical	Surgical and medical procedures	1	0.00 %
Therapy responder	General disorders and administration site conditions	1	0.00 %
Third stage postpartum haemorrhage	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Third trimester pregnancy	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Thoracic cavity drainage	Surgical and medical procedures	1	0.00 %
Thoracic spinal cord paralysis	Nervous system disorders	1	0.00 %
Thrombin-antithrombin III complex abnormal	Investigations	1	0.00 %
Thrombin-antithrombin III complex increased	Investigations	1	0.00 %
Thrombocytopenia neonatal	Blood and lymphatic system disorders	1	0.00 %
Thromboembolectomy	Surgical and medical procedures	1	0.00 %
Thrombosis corpora cavernosa	Reproductive system and breast disorders	1	0.00 %
Thymectomy	Surgical and medical procedures	1	0.00 %
Thyroid calcification	Endocrine disorders	1	0.00 %
Thyroid cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Thyroid dermatopathy	Endocrine disorders	1	0.00 %
Thyroid function test normal	Investigations	1	0.00 %
Thyroid haemorrhage	Endocrine disorders	1	0.00 %
Thyrotoxic periodic paralysis	Endocrine disorders	1	0.00 %
Thyroxine	Investigations	1	0.00 %
Thyroxine free abnormal	Investigations	1	0.00 %
Tidal volume decreased	Investigations	1	0.00 %
Tilt table test positive	Investigations	1	0.00 %
Tissue sealing	Surgical and medical procedures	1	0.00 %
Toe walking	Musculoskeletal and connective tissue disorders	1	0.00 %
Tongue abscess	Infections and infestations	1	0.00 %
Tongue induration	Gastrointestinal disorders	1	0.00 %
Tongue pigmentation	Gastrointestinal disorders	1	0.00 %
Tonsillar exudate	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Tonsillectomy	Surgical and medical procedures	1	0.00 %
Tooth demineralisation	Gastrointestinal disorders	1	0.00 %
Tooth development disorder	Gastrointestinal disorders	1	0.00 %
Tooth dislocation	Injury, poisoning and procedural complications	1	0.00 %
Tooth malformation	Gastrointestinal disorders	1	0.00 %
Tooth pulp haemorrhage	Gastrointestinal disorders	1	0.00 %
Tooth restoration	Surgical and medical procedures	1	0.00 %
Total cholesterol/HDL ratio abnormal	Investigations	1	0.00 %
Total neuropathy score	Investigations	1	0.00 %
Total sperm count decreased	Investigations	1	0.00 %
Toxic anterior segment syndrome	Injury, poisoning and procedural complications	1	0.00 %
Toxic encephalopathy	Nervous system disorders	1	0.00 %
Toxic shock syndrome streptococcal	Infections and infestations	1	0.00 %
Toxicologic test abnormal	Investigations	1	0.00 %
Trace element deficiency	Metabolism and nutrition disorders	1	0.00 %
Tracheal dilatation	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Tracheal haemorrhage	Injury, poisoning and procedural complications	1	0.00 %
Tracheo-oesophageal fistula	Congenital, familial and genetic disorders	1	0.00 %
Tracheomalacia	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Tracheostomy infection	Infections and infestations	1	0.00 %
Tracheostomy tube removal	Surgical and medical procedures	1	0.00 %
Transaminases	Investigations	1	0.00 %
Transcription medication error	Injury, poisoning and procedural complications	1	0.00 %
Transferrin abnormal	Investigations	1	0.00 %
Transferrin saturation	Investigations	1	0.00 %
Transfusion related complication	Injury, poisoning and procedural complications	1	0.00 %
Transient epileptic amnesia	Nervous system disorders	1	0.00 %
Transitional cell carcinoma	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Transplantation complication	Injury, poisoning and procedural complications	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Transurethral bladder resection	Surgical and medical procedures	1	0.00 %
Transvestism	Psychiatric disorders	1	0.00 %
Traumatic delivery	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Traumatic fracture	Injury, poisoning and procedural complications	1	0.00 %
Trematode infection	Infections and infestations	1	0.00 %
Tremor neonatal	Nervous system disorders	1	0.00 %
Treponema test false positive	Investigations	1	0.00 %
Tri-iodothyronine	Investigations	1	0.00 %
Tri-iodothyronine abnormal	Investigations	1	0.00 %
Tri-iodothyronine free abnormal	Investigations	1	0.00 %
Trichophytosis	Infections and infestations	1	0.00 %
Tricuspid valve prolapse	Cardiac disorders	1	0.00 %
Trigeminal nerve injection	Surgical and medical procedures	1	0.00 %
Triple positive breast cancer	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Trisomy 16	Congenital, familial and genetic disorders	1	0.00 %
Trisomy 8	Congenital, familial and genetic disorders	1	0.00 %
Tropical spastic paresis	Infections and infestations	1	0.00 %
Troponin I normal	Investigations	1	0.00 %
Troponin T	Investigations	1	0.00 %
Truancy	Social circumstances	1	0.00 %
Tubal rupture	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Tuberculoma of central nervous system	Infections and infestations	1	0.00 %
Tuberculosis of central nervous system	Infections and infestations	1	0.00 %
Tuberculous pleurisy	Infections and infestations	1	0.00 %
Tumour ablation	Surgical and medical procedures	1	0.00 %
Tumour associated fever	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Tumour flare	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Tumour perforation	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Tumour pseudoprogression	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Twiddler's syndrome	Injury, poisoning and procedural complications	1	0.00 %
Type 2 lepra reaction	Infections and infestations	1	0.00 %
Ulcerative duodenitis	Gastrointestinal disorders	1	0.00 %
Ulcerative gastritis	Gastrointestinal disorders	1	0.00 %
Ultrasound abdomen abnormal	Investigations	1	0.00 %
Ultrasound kidney abnormal	Investigations	1	0.00 %
Ultrasound liver abnormal	Investigations	1	0.00 %
Ultrasound ovary abnormal	Investigations	1	0.00 %
Ultrasound scan	Investigations	1	0.00 %
Ultrasound scan normal	Investigations	1	0.00 %
Ultrasound thyroid abnormal	Investigations	1	0.00 %
Ultrasound uterus abnormal	Investigations	1	0.00 %
Umbilical cord around neck	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Umbilical cord short	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Umbilical haematoma	Skin and subcutaneous tissue disorders	1	0.00 %
Umbilical haemorrhage	Skin and subcutaneous tissue disorders	1	0.00 %
Underimmunisation	Social circumstances	1	0.00 %
Unemployment	Social circumstances	1	0.00 %
Unevaluable specimen	Investigations	1	0.00 %
Univentricular heart	Congenital, familial and genetic disorders	1	0.00 %
Upper aerodigestive tract infection	Infections and infestations	1	0.00 %
Upper respiratory tract infection bacterial	Infections and infestations	1	0.00 %
Urachal abnormality	Congenital, familial and genetic disorders	1	0.00 %
Urea urine	Investigations	1	0.00 %
Urea urine decreased	Investigations	1	0.00 %
Urea urine increased	Investigations	1	0.00 %
Ureteral disorder	Renal and urinary disorders	1	0.00 %
Ureteral wall thickening	Renal and urinary disorders	1	0.00 %
Urethral atresia	Congenital, familial and genetic disorders	1	0.00 %
Urethral caruncle	Renal and urinary disorders	1	0.00 %
Urethral fistula	Renal and urinary disorders	1	0.00 %
Urethral injury	Injury, poisoning and procedural complications	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Urethral polyp	Renal and urinary disorders	1	0.00 %
Urinary assistance device user	Social circumstances	1	0.00 %
Urinary bladder atrophy	Renal and urinary disorders	1	0.00 %
Urinary bladder haematoma	Renal and urinary disorders	1	0.00 %
Urinary casts present	Investigations	1	0.00 %
Urinary lipids present	Investigations	1	0.00 %
Urinary tract infection pseudomonal	Infections and infestations	1	0.00 %
Urinary tract malformation	Congenital, familial and genetic disorders	1	0.00 %
Urine bilirubin decreased	Investigations	1	0.00 %
Urine bilirubin increased	Investigations	1	0.00 %
Urine chromium increased	Investigations	1	0.00 %
Urine copper increased	Investigations	1	0.00 %
Urine cytology	Investigations	1	0.00 %
Urine oxalate increased	Investigations	1	0.00 %
Urine porphobilinogen increased	Investigations	1	0.00 %
Urine sodium abnormal	Investigations	1	0.00 %
Urine sodium decreased	Investigations	1	0.00 %
Urine uric acid increased	Investigations	1	0.00 %
Urogenital fistula	Renal and urinary disorders	1	0.00 %
Urogenital infection bacterial	Infections and infestations	1	0.00 %
Urticaria vibratory	Skin and subcutaneous tissue disorders	1	0.00 %
Uterine abscess	Infections and infestations	1	0.00 %
Uterine adhesions	Reproductive system and breast disorders	1	0.00 %
Uterine cervix hyperplasia	Reproductive system and breast disorders	1	0.00 %
Uterine dilation and evacuation	Surgical and medical procedures	1	0.00 %
Uterine injury	Injury, poisoning and procedural complications	1	0.00 %
Uterine irritability	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Uterine ischaemia	Reproductive system and breast disorders	1	0.00 %
Uterine neoplasm	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Uterine operation	Surgical and medical procedures	1	0.00 %
Uterine rupture	Injury, poisoning and procedural complications	1	0.00 %
Uveal prolapse	Injury, poisoning and procedural complications	1	0.00 %
Uvula deviation	Gastrointestinal disorders	1	0.00 %
Vaccination site laceration	General disorders and administration site conditions	1	0.00 %
Vaccine associated paralytic poliomyelitis	Infections and infestations	1	0.00 %
Vaccine bacteria shedding	Infections and infestations	1	0.00 %
Vaccine virus shedding	Infections and infestations	1	0.00 %
Vaginal cancer recurrent	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Vaginal fistula	Reproductive system and breast disorders	1	0.00 %
Vaginal pH abnormal	Investigations	1	0.00 %
Vaginal pH increased	Investigations	1	0.00 %
Vaginal polyp	Reproductive system and breast disorders	1	0.00 %
Vaginal prolapse	Reproductive system and breast disorders	1	0.00 %
Vagotomy	Surgical and medical procedures	1	0.00 %
Vanishing twin syndrome	Pregnancy, puerperium and perinatal conditions	1	0.00 %
Variant Creutzfeldt-Jakob disease	Infections and infestations	1	0.00 %
Varicella zoster oesophagitis	Infections and infestations	1	0.00 %
Varicose veins of abdominal wall	Gastrointestinal disorders	1	0.00 %
Vascular access complication	Injury, poisoning and procedural complications	1	0.00 %
Vascular access site dissection	Injury, poisoning and procedural complications	1	0.00 %
Vascular access site swelling	Injury, poisoning and procedural complications	1	0.00 %
Vascular anastomosis	Surgical and medical procedures	1	0.00 %
Vascular catheterisation	Surgical and medical procedures	1	0.00 %
Vascular cognitive impairment	Nervous system disorders	1	0.00 %
Vascular compression therapy	Surgical and medical procedures	1	0.00 %
Vascular dissection	Vascular disorders	1	0.00 %
Vascular endothelial growth factor overexpression	Congenital, familial and genetic disorders	1	0.00 %
Vascular graft	Surgical and medical procedures	1	0.00 %
Vascular graft stenosis	Injury, poisoning and procedural complications	1	0.00 %
Vascular operation	Surgical and medical procedures	1	0.00 %
Vascular parkinsonism	Nervous system disorders	1	0.00 %
Vascular procedure complication	Injury, poisoning and procedural complications	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Vascular resistance pulmonary	Investigations	1	0.00 %
Vascular resistance pulmonary increased	Investigations	1	0.00 %
Vascular shunt	Vascular disorders	1	0.00 %
Vasculitic ulcer	Skin and subcutaneous tissue disorders	1	0.00 %
Vasculitis gastrointestinal	Gastrointestinal disorders	1	0.00 %
Vegan	Social circumstances	1	0.00 %
Vehicle solution use	Surgical and medical procedures	1	0.00 %
Velopharyngeal incompetence	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Vena cava injury	Injury, poisoning and procedural complications	1	0.00 %
Venogram	Investigations	1	0.00 %
Venogram abnormal	Investigations	1	0.00 %
Venoocclusive disease	Vascular disorders	1	0.00 %
Venous bruit	Investigations	1	0.00 %
Venous pressure	Investigations	1	0.00 %
Venous pressure increased	Investigations	1	0.00 %
Venous pressure jugular	Investigations	1	0.00 %
Venous recanalisation	Vascular disorders	1	0.00 %
Ventilation/perfusion scan	Investigations	1	0.00 %
Ventricular asystole	Cardiac disorders	1	0.00 %
Ventricular drainage	Surgical and medical procedures	1	0.00 %
Ventricular internal diameter abnormal	Investigations	1	0.00 %
Ventricular remodelling	Cardiac disorders	1	0.00 %
Verbigeration	Psychiatric disorders	1	0.00 %
Vertebral artery hypoplasia	Congenital, familial and genetic disorders	1	0.00 %
Vertebral end plate inflammation	Musculoskeletal and connective tissue disorders	1	0.00 %
Vertebrobasilar dolichoectasia	Nervous system disorders	1	0.00 %
Very low density lipoprotein increased	Investigations	1	0.00 %
Vesicoureteric reflux	Renal and urinary disorders	1	0.00 %
Vessel perforation	Vascular disorders	1	0.00 %
Vessel puncture site inflammation	General disorders and administration site conditions	1	0.00 %
Vessel puncture site reaction	General disorders and administration site conditions	1	0.00 %
Vestibular nystagmus	Nervous system disorders	1	0.00 %
Vestibular paroxysmia	Ear and labyrinth disorders	1	0.00 %
Vestibuloplasty	Surgical and medical procedures	1	0.00 %
VEXAS syndrome	Congenital, familial and genetic disorders	1	0.00 %
Viral corneal ulcer	Infections and infestations	1	0.00 %
Viral keratouveitis	Infections and infestations	1	0.00 %
Viral parotitis	Infections and infestations	1	0.00 %
Viral rhinitis	Infections and infestations	1	0.00 %
Viral uveitis	Infections and infestations	1	0.00 %
Viral vasculitis	Infections and infestations	1	0.00 %
Visceral leishmaniasis	Infections and infestations	1	0.00 %
Visual acuity tests	Investigations	1	0.00 %
Visual agnosia	Nervous system disorders	1	0.00 %
Visual evoked potentials abnormal	Investigations	1	0.00 %
Vital capacity	Investigations	1	0.00 %
Vital signs measurement	Investigations	1	0.00 %
Vitamin B1 decreased	Investigations	1	0.00 %
Vitamin B1 increased	Investigations	1	0.00 %
Vitamin D	Investigations	1	0.00 %
Vitamin supplementation	Surgical and medical procedures	1	0.00 %
Vitrectomy	Surgical and medical procedures	1	0.00 %
Vitreous haematoma	Eye disorders	1	0.00 %
Vitreous injury	Injury, poisoning and procedural complications	1	0.00 %
Vitreous prolapse	Eye disorders	1	0.00 %
Vocal cord atrophy	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Vocal cord cyst	Respiratory, thoracic and mediastinal disorders	1	0.00 %
Volume blood	Investigations	1	0.00 %
Volume blood decreased	Investigations	1	0.00 %
Voluntary redundancy	Social circumstances	1	0.00 %
Volvulus of small bowel	Gastrointestinal disorders	1	0.00 %
Vomiting psychogenic	Psychiatric disorders	1	0.00 %
Von Willebrand's factor activity decreased	Investigations	1	0.00 %

(continued)

Preferred Term	System Organ Class (SOC)	Number of cases	Percentage (%)
Von Willebrand's factor antigen increased	Investigations	1	0.00 %
Vulval haematoma	Reproductive system and breast disorders	1	0.00 %
Vulvar dysplasia	Reproductive system and breast disorders	1	0.00 %
Vulvar erosion	Reproductive system and breast disorders	1	0.00 %
Vulvectomy	Surgical and medical procedures	1	0.00 %
Vulvovaginal exfoliation	Reproductive system and breast disorders	1	0.00 %
Vulvovaginal warts	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Waldenstrom's macroglobulinaemia stage III	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %
Walled-off pancreatic necrosis	Gastrointestinal disorders	1	0.00 %
Wallerian degeneration	Nervous system disorders	1	0.00 %
Wandering pacemaker	Cardiac disorders	1	0.00 %
Waterhouse-Friderichsen syndrome	Infections and infestations	1	0.00 %
Waxy flexibility	Psychiatric disorders	1	0.00 %
Weight	Investigations	1	0.00 %
Wernicke's encephalopathy	Nervous system disorders	1	0.00 %
West Nile viral infection	Infections and infestations	1	0.00 %
West Nile virus test positive	Investigations	1	0.00 %
Wheat-free diet	Surgical and medical procedures	1	0.00 %
White blood cell analysis abnormal	Investigations	1	0.00 %
White blood cell count normal	Investigations	1	0.00 %
Williams syndrome	Congenital, familial and genetic disorders	1	0.00 %
Withdrawal of life support	Surgical and medical procedures	1	0.00 %
Wolf-Hirschhorn syndrome	Congenital, familial and genetic disorders	1	0.00 %
Wound closure	Surgical and medical procedures	1	0.00 %
Wound contamination	Injury, poisoning and procedural complications	1	0.00 %
Wound drainage	Surgical and medical procedures	1	0.00 %
Wound infection bacterial	Infections and infestations	1	0.00 %
Wound infection fungal	Infections and infestations	1	0.00 %
Wound treatment	Surgical and medical procedures	1	0.00 %
Writer's cramp	Nervous system disorders	1	0.00 %
Wrong dosage formulation	Injury, poisoning and procedural complications	1	0.00 %
Wrong patient	Injury, poisoning and procedural complications	1	0.00 %
Wrong product stored	Injury, poisoning and procedural complications	1	0.00 %
Wrong strength	Injury, poisoning and procedural complications	1	0.00 %
X-linked lymphoproliferative syndrome	Congenital, familial and genetic disorders	1	0.00 %
X-ray gastrointestinal tract abnormal	Investigations	1	0.00 %
X-ray limb abnormal	Investigations	1	0.00 %
X-ray with contrast upper gastrointestinal tract	Investigations	1	0.00 %
XXX syndrome	Congenital, familial and genetic disorders	1	0.00 %
Yellow fever	Infections and infestations	1	0.00 %
Yellow nail syndrome	Skin and subcutaneous tissue disorders	1	0.00 %
Yersinia bacteraemia	Infections and infestations	1	0.00 %
Yolk sac tumour site unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0.00 %